

U.S. Department of Health and Human Services
Office of the Secretary
Office of the Assistant Secretary for Health



IN THIS ISSUE

COMMUNITY VOICES

Perspectives from UCSF's RIO

INSIDE ORI

Keeping the Records Straight:
Spotlight on ORI's Confidential File Room

FROM THE DESK OF DR. JOHN DAHLBERG

The Makings of a Successful
ORI Scientist-Investigator

3 Tips for
RIOs

UPCOMING EVENTS

New Funding Opportunities
Conferences and Workshops
Job Openings at ORI

New Horizons

Along with its completely new look, this edition of the newsletter highlights several changes to ORI's programs. ORI's upcoming conferences will focus on clinical research misconduct and emerging international themes. The restructured extramural research program emphasizes fresh approaches to research integrity and will offer conference grants for the first time. We also welcome two new scientist-investigators to our team and give you an insider's glimpse behind the scenes at ORI.

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Message from the Director

November 21, 2014



Dear Readers,

In my primary role as Director of the Office of Disease Prevention and Health Promotion (ODPHP), I oversee initiatives such as Healthy People 2020 and Dietary and Physical Activity Guidelines that seek to inform policy decisions, educate our public, and ultimately improve health outcomes in our communities. Although the Office of Research Integrity (ORI) has a distinctly different mission, I am struck by the impact of ORI's work on public health. By regulating research funded by the U.S. Public Health Service, ORI ensures that our nation's research is conducted with the utmost integrity and reported honestly to the public. This, in turn, fosters public trust in research that serves as the foundation of all public health programs.

Along with our website, annual reports, and other communications, ORI's newsletter contributes to strengthening the public trust in research by providing transparency. We have changed not only the look of our newsletter, but also the focus. This and future issues will explore topics related to ORI's responsibility and capacity to serve the research community. Specifically, we will summarize new research misconduct findings, unveil upcoming events, and offer helpful insights for improving the quality of research and handling of research misconduct allegations. Even more, we hope to inspire you to join us in preventing research misconduct, protecting whistleblowers, and promoting research integrity.

Sincerely,

Don Wright

Donald Wright, MD, MPH
Acting Director, ORI
Director, ODPHP

DIO Director's Column



Susan Garfinkel, Ph.D.

Director, Division of Investigative Oversight (DIO)

In the past year, DIO has received and reviewed 342 allegations by telephone, mail, or e-mail (AskORI@hhs.gov). Of these, 27% were referred to institutions and continued to the inquiry and/or investigation stages. Several allegations were referred to other government offices or agencies. The remaining allegations did not meet ORI's definitional jurisdiction for falsification/fabrication/plagiarism or ORI's funding jurisdiction for U.S. Public Health Service (PHS)-funded research. DIO also closed 71 cases. Twelve cases were closed with findings of research misconduct, four within the last three months, and 59 cases were closed at the assessment, inquiry or investigation stage with no research misconduct findings.

This summer, DIO hired two Scientist-Investigators. In addition, several news stories hit the press about research misconduct globally, and national and international delegations have visited ORI to learn from our 20-year history of handling difficult research misconduct cases. DIO is also strengthening coordination with offices within the U.S. federal government that handle research misconduct, including the Department of the Interior and the National Science Foundation, and partnering with the Office of Inspector General in cases involving grant fraud. Ms. Hammatt and I attended the 2nd annual Association of Research Integrity Officers Meeting in Chicago in September, and are working together to plan several meetings for the research community in the upcoming months.

DEI Director's Column



Zoë Hammatt, J.D., M.Phil.

Director, Division of Education and Integrity (DEI)

Having served as a Research Integrity Officer at the University of Hawaii, I have long held ORI in the highest regard. ORI is renowned for its efforts to increase the public trust in research and promote research integrity across the country and around the world.

Since my arrival in June, I have been even more impressed by the rigor with which DIO investigators analyze misconduct cases and the level and diversity of their scientific expertise. As the new DEI Director, I am excited about the opportunity to expand upon existing educational programs and create new initiatives. For example, we have started an internal seminar series and are planning meetings around specific themes, including "Research Integrity in Asia and the Pacific Rim," "Research Misconduct in Clinical Research" and intensive RIO Boot Camp training for those handling research misconduct allegations.

Recognizing ORI's history of leading research integrity efforts around the world, we are joining the 4th World Conference on Research Integrity in planning for the next gathering in Rio de Janeiro, May 31 - June 3, 2015. This winter we plan to release a new Funding Opportunity Announcement to encourage novel exploration of questions related to research integrity, and, for the first time, ORI will offer conference grants. In this issue, we'd like to share some of our program enhancements, including our redesigned newsletter, which we hope you'll enjoy.

Table of Contents

ORI News Bites	4	Community Voices	7
Job Opportunities	4	Upcoming Conferences and Workshops	8
New Directions for the Research on Research Integrity Program	5	Inside ORI: Behind the Scenes	9
The Makings of a Successful ORI Scientist-Investigator	6	ORI Extramural Program Funds Three New Grants	10
The RIO's Corner	6	Case Summaries of Research Misconduct Findings	11
Two Scientist-Investigators Join DIO	7		

ORI Directors Attend Association of Research Integrity Officers (ARIO) Meeting

Dr. Susan Garfinkel and Ms. Zoë Hammatt were invited to present at the 2nd ARIO meeting hosted by Northwestern University in Chicago on September 30, 2014.

According to Sheila Garrity, Executive Director of Research Integrity and Compliance at George Washington University and co-founder of ARIO, the Chicago meeting was a great success. The ARIO Steering Committee is formalizing the organization and expanding

the list of over more than 400 Research Integrity Officers and their institutional counsel.

Ms. Garrity noted, “this group has already become a valuable network for RIOs to call each other with questions about difficult cases and share best practices,” and “we are thrilled that a group of institutions in Colorado and Wyoming will jointly host the next meeting.” The next ARIO Meeting will be in Colorado, September 27 - 30, 2015.

If you have questions about ARIO, contact:

Lauran Qualkenbush

Director
Office for Research Integrity
Northwestern University
lhane@northwestern.edu

Sheila Garrity

Executive Director
Research Integrity and Compliance
George Washington University
srgarrity@gwu.edu

Japanese Delegation Visits ORI: Seeks to Educate Clinicians and Prevent Misconduct

Five delegates from Japan visited in September to learn from ORI’s 20 years of experience with research misconduct allegations and responsible conduct of research (RCR) training. DIO and DEI staff shared lessons learned about investigative oversight, institutional assurances, and educational resources. The delegation was particularly interested in educating clinical researchers on how to identify and handle misconduct, as well as ORI’s new interactive video, “The Research Clinic,” <http://ori.hhs.gov/TheResearchClinic>.



Dr. Shuichi Kawarasaki, Dr. Yukari Uemura, Dr. Akiko Kishi-Svensson, Dr. Yoshihiro Arakawa, and Dr. Hideki Hanaoka from the University of Tokyo Hospital and Chiba University Hospital pose with ORI staff.

ORI and the Office of Inspector General Partner to Investigate Grant Fraud

ORI collaborates with the HHS Office of Inspector General (OIG) to safeguard Public Health Service (PHS) research funds. While ORI oversees investigations of research misconduct and makes recommendations for administrative actions against guilty respondents, ORI is not responsible for criminal investigations involving research fraud.

In addition to audits and evaluations, the OIG conducts criminal, civil, and administrative investigations of fraud related to HHS programs, operations, and beneficiaries. The OIG Office of Investigations handles grant and contract fraud investigations. These investigations may result in the suspension or debarment of a grantee, contractor or individuals; recovery of money damages and penalties under the False Claims Act or other administrative remedies; or court-ordered criminal restitution and penalties, including incarceration. OIG may receive referrals of potential fraud involving institutions receiving PHS funding from ORI and other HHS awarding agencies and from the general public. The OIG Hotline phone number is 1-800-HHS-TIPS (1-800-447-8477); Fax:1-800-223-8164; TTY:1-800-377-4950 and the mail address is:

U.S. Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
PO Box 23489
Washington, DC 20026

Job Opportunities at ORI

The Division of Education and Integrity will soon post vacancies for two Health Science Administrators (GS14) to contribute to its many activities. Job announcements will be posted on USA-JOBS.gov, ORI website, and ORI’s Twitter. To receive e-mail notification, sign up for ORI’s updates at <http://ori.hhs.gov/email-subscribe>.

A postdoctoral fellowship position also is available at ORI. The fellowship program enables recent graduates to participate in ORI’s innovative research, education, communications, and conference activities. The position is available through the Oak Ridge Institute for Science and Education (ORISE) program: <http://j.mp/ORIphdfellowship>.

EXTRAMURAL RESEARCH PROGRAM



New Horizons for the Research on Research Integrity Program

Two new funding mechanisms will support research grants and conferences in FY2015

To increase the cadre of researchers exploring critical questions related to research integrity, ORI is restructuring its Research on Research Integrity (RRI) Program. Two funding opportunity announcements are expected to be released in January 2015: one for research grants and one for conference grants.

Research Grants

ORI's RRI program has funded research over the years with the goal of establishing evidence to drive ORI's educational programs and help prevent research misconduct.

As a result of a review of previous studies and research priorities for ORI, the Division of Education and Integrity (DEI) is changing the direction of ORI-funded research, from a primarily descriptive and educational focus to one that is designed explicitly to (a) identify risk factors that make misconduct more likely, (b) create an evidence base for proactive interventions, and (c) build upon lessons learned through previous research and the experiences of those who have been involved in guiding research misconduct investigations. The core assumption is that the social, cultural, and behavioral mechanisms underlying research misconduct must be understood to address the problem.

In previous years, the RRI Program

typically funded \$275,000 for two-year projects. The research program will now be structured in two phases:

Phase I: The objective for Phase I will be to establish project merit and feasibility and to generate preliminary data prior to seeking further support for Phase II. Phase I awards will have a ceiling of \$75,000 for a period of one year. Up to ten Phase I projects will be funded.

Phase II: Phase II will constitute a competition limited to Phase I awardees. Phase II projects will build upon results achieved in Phase I. Funding will be based on success demonstrated in Phase I, the merit and feasibility of the Phase II proposal, and the availability of funds. The two-year Phase II awards will have a ceiling of \$125,000 per year (\$250,000

total).

"This format reflects a fresh approach to broadening the pool of scholars interested in research integrity," said Dr. John Dahlberg, Deputy Director. "With the enhanced RRI program, we hope to eventually have a better sense about what makes individuals engage in misconduct, and, conversely, what makes an honest scientist."

Research with the potential to lead to interventions that can prevent research misconduct will be given the highest priority.

Conference Grants

For the first time, the RRI Program will grant awards for conferences. The funding will provide opportunities for applicants to hold research integrity meetings at various locations across the United States. The conference grant program aims to promote the expansion of the research integrity community and the exploration of cross-disciplinary approaches to studying research integrity.

The program will fund up to five conference grants ranging from \$25,000 to \$50,000.

Notification of release of the RRI FOAs will be posted on Grants.gov, ORI website, Twitter (@HHS_ORI), and via e-mail update (<http://ori.hhs.gov/email-subscribe>).

"With the enhanced RRI program, we hope to eventually have a better sense about what makes individuals engage in misconduct, and, conversely, what makes an honest scientist."

John Dahlberg, Ph.D.

The Makings of a Successful ORI Scientist-Investigator

Although the eight full-time scientist-investigators in the Division of Investigative Oversight (DIO) within ORI have many responsibilities, their primary task is to conduct fair, objective, and independent review of the outcome of inquiries and investigations of allegations of research misconduct carried out by a myriad of institutions. What else do they do? They receive a lot of calls and e-mails seeking guidance, providing allegations of misconduct, and often expressing concern, dismay and anger about their institution’s response to their complaints. Retaliation concerns are often raised. Each of these calls requires patience, thoughtful guidance, and frequently referring the caller to other resources or agencies.

Because ORI must rely on the quality of the institutional review and the content of their reports and attachments, we have reached out to institutions for over seven years to provide Research Integrity Officers (RIOs) and institutional attorneys who deal with misconduct matters with what have been called Boot Camps for RIOs. This has helped create an informal network of officials around the country to make them feel comfortable contacting ORI and each other to seek advice on their cases. DIO investigators receive calls from our institutional colleagues virtually every day.

ORI’s scientist-investigators must be aggressive learners, but also patient in reviewing often voluminous records in their effort to independently confirm, and often expand, the findings of an institution’s investigation committee. This includes becoming facile with sophisticated software programs to allow ORI to strengthen the evidence for or against a finding of misconduct. Although DIO investigators have all conducted research and remain knowledgeable in a wide range of disciplines, sometimes the specialized nature of a case requires DIO to reach out to subject matter experts. Fortunately, we often find these experts among our esteemed colleagues on the nearby NIH campus.

Certain other skills and requirements may be less evident. Our scientist-investigators must be excellent communicators,

both orally and in writing. Our target audience is diverse and includes our attorneys, respondents’ attorneys, and other non-scientists, so we must constantly struggle to minimize the use of scientific terms of art. We may need to work with the Office of Inspector General or attorneys with the Department of Justice to assist them with grant fraud or *qui tam* cases. And in the event ORI must defend its finding in a hearing before an administrative law judge, the scientist-investigator in charge of the case must be prepared to sit in the witness box being cross examined by the respondent’s attorney.

Lastly, and importantly, ORI’s scientist-investigators must effectively interact with each other and the outside academic community, as our collective knowledge and wisdom contributes enormously to the ability of DIO to make consistent and appropriate recommendations to the ORI Director who is responsible for deciding whether research misconduct occurred. The process of reaching consensus on these recommendations has been a core element of ORI’s effectiveness for 25 years.



Dr. John Dahlberg has been with ORI since its inception in 1992 and has handled thousands of allegations of research misconduct. Dr. Dahlberg was appointed Director of the Division of Investigative Oversight in 2006. He now serves as ORI’s Deputy Director.

THE RIO’S CORNER

Three Things RIOs and Their Institutional Counsel Should Remember

- 1 “If a respondent makes an admission, notify ORI”**
 Per 42 C.F.R. Part 93 (§93.316), “an institution must notify ORI in advance if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt...”
 This enables ORI to take appropriate action, including approving closure of the case.
- 2 “Use ORI’s Rapid Response for Technical Assistance Program”**
 ORI’s RRTA program is designed to help RIOs handle research misconduct allegations from start to finish, including framing allegations, writing reports, conducting sequestration, and performing forensic analysis.
 Visit <http://ori.hhs.gov/rapid-response-technical-assistance> for more information.
- 3 “If in doubt, call ORI”**
 Don’t be afraid to contact ORI. ORI scientist-investigators are available to answer questions at any time during an assessment, inquiry, or investigation. Contact AskORI@hhs.gov.

The RIOs’ Corner is intended to address common issues related to handling research misconduct allegations. If you have a specific question, please contact us at AskORI@hhs.gov or (240) 453-8800.

Two Scientist-Investigators Join the Division of Investigative Oversight



Meet Dr. William Trenkle

Dr. William Trenkle became a Scientist-Investigator in August 2014 after serving two years as a Senior Public Health Service Fellow in ORI's Division of Investigative Oversight. Dr.

Trenkle received his B.S. from Alma College, his Ph.D. in Organic Chemistry from the University of California, Irvine, and was an NIH National Research Service Award postdoctoral fellow at Harvard University. Upon completion of his postdoctoral training, Dr. Trenkle started his independent career as a professor in the Chemistry Department at Brown University. Prior to joining ORI, Dr. Trenkle served as the Director of the Chemical Biology Core Facility in the National Institute of Diabetes and Digestive and Kidney Diseases and as a Program Director with the Division of Pharmacology, Physiology and Biological Chemistry in the National Institute of General Medical Sciences. Dr. Trenkle's expertise lies in the areas of organic chemistry, spectroscopy, and chemical biology. At ORI, Dr. Trenkle is the chemistry subject matter expert and consults on forensic analysis of images, electronic evidence and computer files. Dr. Trenkle has been appointed to serve in the new National Institute of Standards and Technology Forensic Sciences, Organization for Scientific Area Committees (OSAC) as a member of the Imaging Technology Subcommittee. OSAC will coordinate development of standards and guidelines to improve quality and consistency of work in the forensic science community.



Meet Dr. Brian Mozer

Dr. Brian Mozer joined ORI as a Scientist-Investigator in March 2013 as contractor and became a full-time employee in August 2014. Dr. Mozer was a senior staff scientist in the intramural research program at the National Heart, Lung, and Blood Institute, NIH, for more than 10 years. At NIH, Dr. Mozer studied synapse maturation and animal models of autism, and was a member of a functional genomics research consortium using RNAi to study nervous system development. Dr. Mozer also worked in the biotech industry, most recently developing RNA-based therapeutics for gene therapy of human diseases. Dr. Mozer is a recognized expert in the use of model organisms to understand biological mechanisms of human disease and has authored 13 peer-reviewed publications. His research expertise includes molecular biology, genetics, transgenic animals, developmental biology and neuroscience.

"I love science, but I don't like it when a few bad researchers ruin the public trust in science."

Brian Mozer, Ph.D.

Perspectives on Handling Institutional Investigations

by Eric Mah, RIO, University of California, San Francisco

Research Integrity Officers at academic institutions sometimes feel challenged in the world of research misconduct. Some common questions I have heard include: what does the Office of Research Integrity expect of us, why are they asking us to do that, and, is this process taking too long?

To help address some of these questions, colleagues from three University of California campuses and I visited the ORI in August at their offices in Rockville, Maryland, for a day-and-a-half workshop.

The workshop included an introduction to some of the forensic tools that ORI applies to different situations and cases, informal conversations with individuals from the Division of Investigative Oversight, and an exposure to educational tools and resources available from ORI to institutions.

My colleagues and I shared with ORI some of the issues faced by academic institutions (e.g., the varying levels of forensic skills and technology available locally), reminded them that while research misconduct was a priority to us—it is not our only institutional responsibility, and probed about the seem-

ingly high bar ORI requires institutions to meet before ORI can reach an official finding of research misconduct.

The visit was very constructive and I left with an energized feeling. While we did not agree on everything, I believed we all had a better understanding of our mutual goals and different—but similar—objectives. ORI was not just requiring work that might on occasion seem excessive to institutions; rather, ORI was trying to build the strongest and most thorough case possible and needs our institutional resources to build that case. Meanwhile, I asked ORI to consider clearly articulating how much evidence is enough in order to meet the burden of proof required for ORI to make a misconduct finding and to consider whether its bar was set at the right level. It appears that perfection could be in some cases be the enemy of progress.

In the end, the visit confirmed that while ORI will always be the regulator and we the regulated community, we can be partners in our approaches, and trust that both sides are doing their best.



Eric Mah, RIO, UCSF

COMMUNITY VOICES

Upcoming Conferences and Workshops

ORI's Conference and Workshop Program has several meetings planned for FY2015. In addition to our ongoing Research Integrity Officer (RIO) Boot Camps, upcoming events will focus on research integrity in a global context and research misconduct in clinical research.

Research Integrity Officer Boot Camps

*Washington, D.C., co-sponsored by the University of Virginia
March 29 – April 1, 2015*

*New York City, co-sponsored by the Icahn School of Medicine at Mount Sinai
April 12 – 15, 2015*

RIOs are responsible for administering institutional policies and procedures for handling research misconduct allegations involving U.S. Public Health Service (PHS) research funds. ORI's RIO Boot Camp training program is unique in providing formalized training for RIOs and their legal counsel. Please contact Tracey Randolph to add your name to ORI's Boot Camp waiting list: Tracey.Randolph@hhs.gov.

Research Integrity in Asia and the Pacific Rim

As the level of research collaboration across Asia and the Pacific Rim increases, more and more institutions are seeking to strengthen their systems for managing research misconduct, particularly given the recent rise in highly publicized misconduct cases. More than 100 institutions in the region receive PHS research funds and are thus required to comply with U.S. regulations. As a follow up to initial planning efforts for a meeting at the University of Hawaii and an informal meeting with about 20 participants at the 3rd World Conference on Research Integrity in Montreal in May 2013, ORI and the University of California, San Francisco are co-hosting a planning meeting in February 2015 that will include representatives from throughout Asia and the Pacific Rim. Invited attendees will plan for a larger meeting in the autumn of 2015, with the goal of bringing together institutional officials from the region for training in handling research misconduct allegations and promoting research integrity.

Contact: Tracey.Randolph@hhs.gov.

Research Misconduct in Clinical Research

In January 2013, ORI, the Office for Human Research Protections, and the Food and Drug Administration co-hosted a meeting of Institutional Review Board (IRB) Chairs and Research Integrity Officers in Washington, D.C. to discuss how best to handle allegations of research misconduct in clinical research. That meeting gave rise to a working group that contributed to the recent publication by Barbara E. Bierer and Mark Barnes in the Hastings Center Report (<http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=6972>). To build upon this momentum, ORI and Johns Hopkins University are co-hosting a planning meeting in December 2014 to develop an agenda for the 2nd IRB/RIO conference to be held in the D.C. area in June 2015. Contact: Tracey.Randolph@hhs.gov.

4th World Conference on Research Integrity

The World Conference on Research Integrity (WCRI), which ORI has supported since its inception, is the premiere global forum for the discussion of research integrity issues. Conferences have been held in Lisbon, Singapore, and Montreal (2007, 2010, and 2013), with attendance from more than 50 countries around the world. The theme of the 4th WCRI, May 31 - June 3, 2015 in Rio de Janeiro, Brazil, is "Research Rewards and Integrity: Improving Systems to Promote Responsible Research." The conference is co-chaired by Melissa Anderson, Ph.D. and Sabine Kleinert, M.D. As a member of the Advisory Board, DEI Director Zoë Hammatt attended a Planning Committee meeting in Minneapolis in October. For more information, visit <http://www.wcri2015.org>.


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Research Integrity 17 Nov
@HHS_ORI

PhD Fellowship available at ORI. Strong background in social and behavior science desired. <http://j.mp/ORIPhdFellowship>



Research Integrity 29 Oct
@HHS_ORI

New research misconduct finding: Bijan Ahvazi. <http://j.mp/1rzQeyN>



Research Integrity 21 Oct
@HHS_ORI

Need \$75,000 seed money for a study related research integrity? <http://j.mp/1w2OAgU> ORI Research Grant Forecast.



Research Integrity 21 Oct
@HHS_ORI

ORI Conference Grant Forecast. <http://j.mp/10iqEJc>. \$50,000 award to hold meeting on research integrity.



Research Integrity 17 Oct
@HHS_ORI

The @WhiteHouse releases conference website for the 2015 White House Conference on Aging. whitehouseconferenceonaging.gov



Research Integrity 7 Oct
@HHS_ORI

Case Study: Joanna must decide whether to enroll one of her patients into a study. Is there a conflict of interest? j.mp/ZbPjxG



Francis S. Collins 17 Sep
@NIHDirector

Researchers: we're looking for your innovative ideas for training modules to enhance data reproducibility: <http://1.usa.gov/1pjiWTx> #NIH

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INSIDE ORI - BEHIND THE SCENES


Keeping the Records Straight: Spotlight on Kyle Synan and Ray Fisher

Kyle Synan and Ray Fisher both joined ORI in 2003. At that time, ORI was in the midst of handling its most high profile case. The case involved Dr. Eric Poehlman, who falsified and fabricated his menopause, obesity, and metabolism research data for over a decade. The Federal government banned Dr. Poehlman from NIH funding for life and sentenced him to Federal prison for one year.

“I didn’t realize the magnitude of the case until several years later, after the case was closed and the media covered the story,” said Ray. “When a case is ongoing, we focus on our job and not the media attention the case may get when it’s done.”

As the program assistants for the Division of Investigative Oversight (DIO), Kyle and Ray worked diligently alongside ORI’s scientist-investigators on the Poehlman case. Their task was to maintain meticulous case records, receiving, storing, assessing, and recording all data into an electronic case tracking system.

“The Poehlman case was incredibly complicated and there was a substantial research record,” said Dr. John Dahlberg, who was ORI’s lead investigator on the case. “Kyle and Ray worked flawlessly in the background. They made sure the documents flowed seamlessly between ORI and Department of Justice attorneys working on the case, which helped lead to the federal prison sentence.”

Since 2003, Kyle and Ray have been instrumental in maintaining records for over 2,000 allegations of research misconduct. “Their workload is daunting,” said Susan Garfinkel, DIO

Director. “They process thousands of pages of case-related documents each year.” We interviewed Kyle and Ray to shed light on their important work at ORI.

What made you decide to enter the Federal workforce?

Kyle: I actually started working for the government when I was a sophomore in high school. I worked at a USDA (United States Department of Agriculture) farm as part of a work-study program. Then I started working at the USDA’s National Agriculture Library for about eight years. That’s where I learned organizational skills that I still use today at ORI.

Ray: I worked for two successful private companies before coming to ORI, but I was inspired by my father to become a public servant. My father worked at the USDA and received recognition for his important role in the development of the Beltsville Agricultural Research Center. He worked hard and took his job seriously. He taught me to take pride in my work, and I enjoy what I do.

Tell us about your typical day.

Ray: For us, there’s nothing typical about our typical day. There’s always something different going on. Correspondence, records, and evidence for every case comes across our desks. We summarize all case-related documentation. On any given day, we may summarize up to 100 pieces of correspondence that ORI investigators generate. That’s on top of retrieving reports for the investigators and maintaining chain of custody for evidence and other confidential records.

Kyle: We basically work non-stop. We handle every allegation and case that ORI receives. Each case can involve hundreds of documents and correspondence that need to be reviewed and recorded. It can be a hectic job. I actually get worried when things are slow because it usually means that something big is about happen.

“I tell my son that you should learn something every day even if you aren’t required to learn it at school. Get something out of each day, whether in school, a conversation, or a location.”

Ray Fisher

... SPOTLIGHT continued on page 10

...SPOTLIGHT continued from page 9

What are some memorable cases you have worked on?

Kyle: To tell you the truth, we work on so many ongoing cases that I force myself to forget about the older cases to make room in my head for the new ones. The ones I remember most are the ones where the respondent, and even sometimes the institution, dumps a massive amount of records on ORI to try to delay the process. That strategy typically doesn't work, though.

Ray: I usually remember the cases with the most documentation. The Poehlman case is a good example. It had 10 years' worth of misconduct. There was so much documentation to review, record, and file. There are also cases in which the respondent does unusual things to try to get out of the allegation. Those can be crazy.

How do you ensure the records are handled properly?

Ray: How we handle records is very similar to how scientists are supposed to handle data. We use a checklist and make sure we document everything we do.

Kyle: We have protocols for everything we do, and I follow them. We handle confidential information and evidence that's important to a case so I double check everything I do. Confidentiality is always important, but it's especially important for respondents where there's no finding of misconduct. It's extremely important that we communicate directly with the institution, the respondent, or the respondent's lawyer and never to a third party.

What impact does your work have on cases?

Kyle: We have to be very careful with how we handle the records. The worst case scenario for not properly handling records is that a case can be thrown out on a technicality. I wouldn't want to be responsible for something like that happening.

Ray: Our work affects the efficiency of how a case is handled.

There's a huge volume of records, and we organize them into over 20 different categories. We assist the investigators by being organized and giving them quick access to case records.

What is it like to work at ORI?

Ray: ORI is an interesting place with intelligent people who are knowledgeable about their jobs. Interestingly, they are not as uptight as you might think. We get along and enjoy doing our jobs.

Kyle: It's enjoyable and never boring. Compared to other jobs I've had, the impact of what we do here is more immediate, especially when we make a finding of misconduct.

What have you learned about research integrity that you would share with researchers?

Kyle: Maintain accurate records and be accountable for your work. Keep written documentation in case you're ever questioned about what you've done. Don't let intimidation stop you from talking to someone if you suspect misconduct.

Ray: If there is an issue you're concerned about, go with your hunch and talk to someone about it. Make sure you have dates and notes to document your part in the research.

What is something most people don't know about you?

Ray: I love to play cards, especially Spades.

Kyle: I sing reggae, soca, and the blues when nobody is around.

"It can be a hectic job. I actually get worried when things are slow because it usually means that something big is about happen."

Kyle Synan

ORI Extramural Program Funds Three New Grant Awards

ORI recently awarded \$1,508,376 to support three new and five continuing research projects designed to elucidate factors related to research integrity.

Since 2001, the Research on Research Integrity (RRI) program has funded nearly \$20 million in grant awards to support empirical research on factors that affect integrity in research. ORI granted the following awards in August 2014:

"Course Characteristics and Criteria: A Meta-analytic Approach for Appraising the Effectiveness of RCR Educational Resources"

*Michael Mumford
Board of Regents of the University of Oklahoma*

Abstract

Over the years, a variety of instructional methods and instructional materials

have been developed to support educational interventions in the responsible conduct of research (RCR). Moreover, a fair number of these RCR programs have been evaluated. In the proposed effort, available evaluation data will be used to establish the degree of effectiveness of instructional methods and materials. Results will inform the development of a general model describing key attributes of effective RCR courses. Additionally, procedures for evaluating RCR programs based on these attributes will be developed and the reliability and validity of these procedures will be established. These procedures will be used, in conjunction with the model of RCR instruction, to predict the effectiveness of instructional programs available for evaluation. Following validation of these procedures, and the model, we will develop a predictive tool to model likely effects of instructional interventions on

student learning and performance in RCR education. This application will also allow RCR instructors to estimate the effects of planned instructional interventions and appraise the likely effectiveness of instructional materials.

"Moral Intensity and Rational Choice as Predictors of Research Misconduct"

*Anita M. Gordon
University of Northern Iowa*

Abstract

The goal of this project is to examine the ethical decision-making process in scientific research. It addresses the 4th focus area identified in the FOA as conducting theory-based research "to understand the factors that cause irresponsible and deviant research behaviors." It is basic research, which as noted in the FOA, is quite lacking and needed in

...NEW AWARDS continued on page 11

...NEW AWARDS continued from page 10

order to lay the groundwork for designing effective interventions. Using four theoretical frameworks - the Rest, et.al. (1984) model of moral decision-making, Rational Choice Theory, Organizational Justice, and the Jones (1991) Moral Intensity model – the study will examine moral and rational decision-making by faculty from psychology, sociology, social work, and biology. A unique feature of the study design will be the targeting of faculty from post-baccalaureate comprehensive universities as well as research-intensive institutions. In addition, the sample of 5,000 researchers will be invited to participate via one of five sampling methodologies, including mailed paper, online, and mixed modes, with and without personal telephone contacts. Respondents will assess scenarios depicting more and less serious forms of scientific misconduct (e.g., falsification of data, courtesy authorship), and regression analysis will be used to predict respondent perceptions regarding the likelihood they themselves would take the same actions as those shown in the scenarios. The outcomes of the study will be: (a) estimates of the perceived probabilities of misconduct by researchers in selected disciplines and types of institutions, and across FFP

and QRP scenarios, some of which have not previously been examined; and (b), a better theory-based understanding of how important certain individual and situational factors are in researcher decision-making. Products will include three scientific articles, a comparable number of presentations at national conferences, and a study instrument, related materials, and two de-identified data sets to be deposited in a publicly-accessible online institutional repository.

“The Role of Culture and Experience in the Perception of Research Regulations, Norms, and Values”

*James Dubois
 Washington University in St. Louis*

Abstract

In this proposal we respond to the Funding Opportunity Announcement’s call for “research questions that challenge and test theoretical perspectives on researchers’ integrity behaviors” as it examines “factors that lead researchers to deviate from, or adhere to, the norms of science.” More specifically, we propose to examine how foreign-born and US-born researchers working in the US perceive rules and values in science and how this affects professional decision-making in research, which includes considering rules for research integrity.

With a sample of 200 independent investigators and trainees funded by the NIH (100 foreign-born from Asia and 100 US-born), we will test the hypothesis that perceptions of diverse kinds of rules—regulations, norms of science, and questionable research practices—vary by cultural background (operationalized as nation of origin) and level of experience. We will also examine the impact of the perception of rules on professional decision-making in research, and explore mechanisms that would explain the impact of culture (in terms of values, experience in US, acculturation, personality traits, or exposure to unethical events). We will develop and validate two new measures for this project: The Evaluating Rules and Norms of Science Task (ERNST) and the Rating Values of Science Task (RVST). The new measures will be useful in research and in educational contexts insofar as they will provide researchers, instructors, and trainees with important information regarding the understanding of rules for research within the US cultural context. By identifying factors that might be addressed through tailored educational interventions that go beyond teaching the content of rules, the project will contribute to efforts to preventing research misconduct.



CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

Since June 2014, ORI has made five findings of research misconduct. All five cases involved intentional falsification of data and resulted in voluntary settlement agreements. Melanie Cokinos was debarred from Public Health Service (PHS) research for three years. All others agreed to have any PHS-supported research supervised, have their work certified by their institutions, and exclude themselves from serving in any advisory capacity to PHS.

**Melanie Cokinos
 Southern Research Institute**

Based on the report of an investigation conducted by Southern Research Institute (SRI) and additional analysis conducted by ORI in its oversight review, ORI found that Ms. Melanie Cokonis, for-

mer Research Technician, SRI, engaged in research misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), contracts N01-AI-30047 (HHSN2722011000009C) and N01-AI-70042 (HHSN272200700042C), and National Human Genome Research Institute (NHGRI), NIH, grant U54 HG005034.

ORI found that the Respondent engaged in research misconduct by falsifying assay data that were submitted in reports to NIH. Specifically, ORI found that Respondent knowingly falsified data for cytoprotection assays with antiviral compounds and provided the false data for inclusion in reports submitted to NIH for contracts N01-AI-30047 and N01-AI-70042 and grant

U54 HG005034. Respondent transferred raw data from 8X12 SoftmaxPro matrix files into spreadsheets and then falsified the numbers for cell control, virus control, drug cytotoxicity, drug only, and/or cells+ virus+ drug wells to make 206 assays appear to have been successfully performed when they were not.

Ms. Cokonis has voluntarily agreed for a period of three (3) years, beginning on May 29, 2014:

- (1) to exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as “covered transactions” pursuant to HHS’ Imple-

...SUMMARIES continued on page 12

CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

...SUMMARIES continued from page 11

mentation (2 C.F.R. Part 376 et seq) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the “Debarment Regulations”); and

(2) to exclude herself voluntarily 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.

Jun Fu

**University of Texas
MD Anderson Center**

Based on the Respondent’s admission, the report of an inquiry conducted by the University of Texas MD Anderson Cancer Center (MDACC), and analysis conducted by ORI in its oversight review, ORI found that Dr. Jun Fu, former Post-doctoral Fellow, Department of Neuro-Oncology, MDACC, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants CA56041 and CA127001.

The Respondent has admitted to knowingly and intentionally falsifying Figure 8a in the following publication:

“Novel HSP90 inhibitor NVP-HSP990 targets cell-cycle regulators to ablate Olig2-positive glioma tumor-initiating cells.” *Cancer Res.* 73(10):3062-74, 2013 May 15.

Specifically, the Respondent falsified survival times of mice to show that NVP-HSP990 prolonged survival rates in glioblastoma tumor bearing mice when experimental data were incomplete and unusable. As a result of its inquiry, MDACC has recommended that the senior author of this paper take any appropriate steps with the journal to correct the scientific literature.

Dr. Fu has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on July 15, 2014:

(1) to have his research supervised;

Respondent agrees that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent’s participation is proposed and prior to Respondent’s participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent’s duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent’s research; Respondent agrees that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself voluntarily 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.

Makoto Suzuki

**University of Texas
Southwestern Medical Center**

Based on the report of an investigation conducted by the University of Texas Southwestern Medical Center (UT Southwestern) and analysis conducted by ORI in its oversight review, ORI found that Dr. Makoto Suzuki, currently a Professor in the Department of Thoracic Surgery, Kumamoto University Hospital, Kumamoto, Japan, and formerly a Visiting Scientist in the Hamon Center for Therapeutic Oncology Research, UT Southwestern, engaged in research misconduct in research supported by National Cancer

Institute (NCI), National Institutes of Health (NIH), grants P50 CA070907 and U01 CA084971.

ORI found that Respondent knowingly, intentionally, and recklessly falsified data reported in six (6) publications:

- Suzuki, M., Hao, C., Takahashi, T., Shigematsu, H., Shivapurkar, N., Sathyanarayana, U.G., Iizasa, T., Fujisawa, T., Hiroshima, K., & Gazdar, A.F. “Aberrant methylation of SPARC in human lung cancers.” *Br J Cancer* 92(5):942-8, 2005 Mar 14 (hereafter referred to as “BJC 2005-1”); Retraction in: *Br J Cancer* 108(3):744, 2013 Feb 19;

- Suzuki, M., Shigematsu, H., Shames, D.S., Sunaga, N., Takahashi, T., Shivapurkar, N., Iizasa, T., Frankel, E.P., Minna, J.D., Fujisawa, T., & Gazdar, A.F. “DNA methylation associated inactivation of TGFbeta-related genes DRM/Gremlin, RUNX3, and HPP1 in human cancers.” *Br J Cancer* 93(9):1029-37, 2005 Oct 31 (hereafter referred to as “BJC 2005-2”); Retraction in: *Br J Cancer* 109(12):3132, 2013 Dec 10;

- Suzuki, M., Shigematsu, H., Takahashi, T., Shivapurkar, N., Sathyanarayana, U.G., Iizasa, T., Fujisawa, T., & Gazdar, A.F. “Aberrant methylation of Reprimo in lung cancer.” *Lung Cancer* 47(3):309-14; 2005 Mar (hereafter referred to as “LC 2005”); Retraction in: *Lung Cancer* 85(2):337, 2014 August;

- Suzuki, M., Toyooka, S., Shivapurkar, N., Shigematsu, H., Miyajima, K., Takahashi, T., Stastny, V., Zern, A.L., Fujisawa, T., Pass, H.I., Carbone, M., & Gazdar, A.F. “Aberrant methylation profile of human malignant mesotheliomas and its relationship to SV40 infection.” *Oncogene* 24(7):1302-8, 2005 Feb 10 (hereafter referred to as “ONC 2005”); Retraction in: *Oncogene* 33(21):2814, 2014 May 22;

- Suzuki, M., Shigematsu, H., Shivapurkar, N., Reddy, J., Miyajima, K., Takahashi, T., Gazdar, A.F., & Frenkel, E.P. “Methylation of apoptosis related genes in the pathogenesis and prognosis of prostate cancer.” *Cancer Lett.* 242(2):222-30, 2006 Oct 28 (hereafter referred to as “CL

...SUMMARIES continued on page 13

CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

...SUMMARIES continued from page 12

2006"); and

- Suzuki, M., Shigematsu, H., Shames, D.S., Sunaga, N., Takahashi, T., Shivapurkar, N., Iizasa, T., Minna, J.D., Fujisawa, T., & Gazdar, A.F. "Methylation and gene silencing of the Ras-related GTPase gene in lung and breast cancers." *Ann Surg Oncol.* 14(4):1397-404, 2007 Apr (hereafter referred to as "ASO 2007").

Respondent falsified data representing glyceraldehyde 3-phosphate dehydrogenase (GAPDH) loading controls and methylated/unmethylated polymerase chain reaction (PCR) in reverse transcription-PCR (RT-PCR) gel panels.

Specifically, ORI found by a preponderance of the evidence that Respondent engaged in research misconduct by knowingly, intentionally, and recklessly falsely reporting the results of RT-PCR experiments by:

1. reusing and relabeling an image and claiming it represents different experiments of human tumor cell lines subjected to different treatments; specifically, an identical image was used to represent the:

- (a) GAPDH RT-PCR panels in *BJC* 2005-01, Figure 1A, lanes 4-12, and Figure 1C, lanes 4-12;

- (b) GAPDH RT-PCR panels in *BJC* 2005-2, Figures 1A and 1B, and *ASO* 2007, Figures 1A and 1B; and

- (c) unmethylated form of p16 (p16U) RT-PCR panel in *CL* 2006, Figure 1, lanes 3-10, positive (P) and negative (N) controls, and the p16 U RT-PCR panel in *ONC* 2005, Figure 2A.

2. manipulating an image and claiming it represents a gel with contiguous lanes; specifically, the RT-PCR products in the lanes of gels were cropped, spliced, and pasted together to form a single image for the:

- (a) GAPDH RT-PCR panels in *LC* 2005, Figures 1A and 1B;

- (b) methylated form of Decoy receptor 2 (DcR2 M) methylation-specific PCR (MSP) panel in *CL* 2006, Figure 1; and

- (c) methylated form of small Ras-related GTPase (RRAD M) MSP panel in *ASO* 2007, Figure 3B.

Dr. Suzuki has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on August 26, 2014:

- (1) to have his research supervised; Respondent agrees that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project in which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research; Respondent agrees that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

- (2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and,

- (3) to exclude himself voluntarily 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.

Takao Takahashi
University of Texas
Southwestern Medical Center

Based on the report of an investigation conducted by the University of Texas Southwestern Medical Center (UT South-

western) and analysis conducted by ORI in its oversight review, ORI found that Dr. Takao Takahashi, currently a faculty member in the Department of Surgical Oncology, Gifu University, Graduate School of Medicine, Gifu, Japan, and formerly a Visiting Scientist in the Hamon Center for Therapeutic Oncology Research, UT Southwestern, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant U01 CA084971.

ORI found that Respondent knowingly, intentionally, and recklessly falsified data reported in four (4) publications:

- Takahashi, T., Shivapurkar, N., Reddy, J., Shigematsu, H., Miyajima, K., Suzuki, M., Toyooka, S., Zöchbauer-Müller, S., Drach, J., Parikh, G., Zheng, Y., Feng, Z., Kroft, S.H., Timmons, C., McKenna, R.W., & Gazdar, A.F. "DNA methylation profiles of lymphoid and hematopoietic malignancies." *Clin Cancer Res.* 10(9):2928-35, 2004 May 1 (hereafter referred to as "CCR 2004"); Retraction in: *Clin Cancer Res.* 19(1):307, 2013 Jan 1;

- Takahashi, T., Suzuki, M., Shigematsu, H., Shivapurkar, N., Echebiri, C., Nomura, M., Stastny, V., Augustus, M., Wu, C.W., Wistuba, I.I., Meltzer, S.J., & Gazdar, A.F. "Aberrant methylation of Reprimo in human malignancies." *Int J Cancer* 115(4):503-10, 2005 Jul 1 (hereafter referred to as "IJC 2005"); Retraction in: *Int J. Cancer* 132(2):498, 2013, Jan 15;

- Takahashi, T., Shigematsu, H., Shivapurkar, N., Reddy, J., Zheng, Y., Feng, Z., Suzuki, M., Noomura, M., Augustus, M., Yin, J., Meltzer, S.J., & Gazdar, A.F. "Aberrant promoter methylation of multiple genes during multistep pathogenesis of colorectal cancers." *Int J Cancer* 118(4):924-31, 2006 Feb 15 (hereafter referred to as "IJC 2006"); Retraction in: *Int J Cancer* 132(2):499, 2013 Jan 15; and

- Tokuyama, Y., Takahashi, T., Okumura, N., Nonaka, K., Kawaguchi, Y., Yamaguchi, K., Osada, S., Gazdar, A., & Yoshida, K., "Aberrant methylation of heparan sulfate glucosamine 3-O-sulfotransferase

...SUMMARIES continued on page 14

CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

...SUMMARIES continued from page 13

2 genes as a biomarker in colorectal cancer." *Anticancer Res.* 30(12):4811-8, 2010 Dec (hereafter referred to as "AR 2010"); Retraction in: *Anticancer Res.* 32(11):5138, 2012 Nov.

Respondent falsified data representing glyceraldehyde 3-phosphate dehydrogenase (GAPDH) loading controls and methylated/unmethylated polymerase chain reaction (PCR) in reverse transcription-PCR (RT-PCR) gel panels.

Specifically, ORI found by a preponderance of the evidence that Respondent engaged in research misconduct by knowingly, intentionally, and recklessly falsely reporting the results of RT-PCR experiments by:

1. reusing and relabeling an image and claiming it represents different experiments of human tumor cell lines subjected to different treatments; specifically, an identical image was used to represent the:

(a) GAPDH RT-PCR panels of several lymphoma, leukemia, multiple myeloma, and colorectal cancer cell lines in CCR 2004, Figures 1A and 1B, IJC 2005, Figure 1A, IJC 2006, Figures 1A and 2A, and AR 2010, Figure 1A;

(b) GAPDH RT-PCR panels of the lymphoma cell lines BC-1 and Raji in CCR 2004, Figure 1B, lanes 1-3, and the colorectal cancer cell lines HCT116 and COLO201 in AR 2010, Figure 1C, lanes 4-6;

(c) unmethylated form of p16 (p16UM) controls in the methylation-specific PCR (MSP) panels for the leukemia (Le) and multiple myeloma (MM) samples in CCR 2004, Figure 2; and

(d) p16UM MSP panels for the lymphoma (Ly) and Le samples in CCR 2004, Figure 2, and the unmethylated (UM) bands MSP panel for the colorectal cancer (CRC) cell line in IJC 2005, Figure 5.

2. manipulating an image and claiming it represents a gel with contiguous lanes; specifically, the RT-PCR products in the lanes of gels were cropped, spliced, and

pasted together to form a single image for the MSP panels in IJC 2006, Figure 3.

Dr. Takahashi has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on August 26, 2014:

(1) to have his research supervised; Respondent agrees that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project in which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research; Respondent agrees that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself voluntarily 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.

Zhihua Zou Harvard Medical School and Fred Hutchinson Cancer Research Center

Based on the reports of investigations conducted by Harvard Medical School (HMS) and Fred Hutchinson Cancer

Research Center (FHCRC) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Zhihua Zou, former Postdoctoral Fellow, Department of Neurobiology, HMS, and former Staff Scientist, Division of Basic Sciences, FHCRC, engaged in research misconduct in research supported by National Institute of Deafness and Other Communication Disorders (NIDCD), National Institutes of Health (NIH), grants R01 DC001662 and R01 DC004842.

ORI found that Respondent engaged in research misconduct by falsifying data that were included in two (2) publications:

1. Zou, Z., Horowitz, L.F., Montmayeur, J.P., Snapper, S., & Buck, L.B. "Genetic tracing reveals a stereotyped sensory map in the olfactory cortex." *Nature* 414:173-179, 2001 (hereafter referred to as "Nature 2001").

2. Zou, Z., Li, F., & Buck, L.B. "Odor maps in the olfactory cortex." *Proc Natl Acad Sci USA* 102:7724-7729, 2005 (hereafter referred to as "PNAS 2005").

As a result of the investigations, both publications have been retracted.

Specifically, ORI finds that Respondent:

Falsified Figures 2k, 2l, 3a, 3f, 3h, and 3i in Nature 2001 and Figure 5C(b) in PNAS 2005 by manipulating the images to alter the number and location of positively stained cells in the olfactory bulb and olfactory cortex of mice.

Dr. Zou has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on July 9, 2014:

(1) That the administrative actions delineated in (2)-(4) below will be required for three (3) years after the effective date of the Agreement, beginning on the date of Respondent's employment in a research position in which he receives or applies for U.S. Public Health Service (PHS) support; however, if within three (3) years of the effective date of the Agreement, Respondent has not

...continued on page 15



CASE SUMMARIES

...continued from page 14

obtained employment in a research position in which he receives or applies for PHS support, the administrative actions in (2)-(4) will no longer apply;

(2) to have any PHS-supported research supervised; Respondent agrees that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research; Respondent agrees that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and

approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan; (3) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and (4) to exclude himself voluntarily 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.



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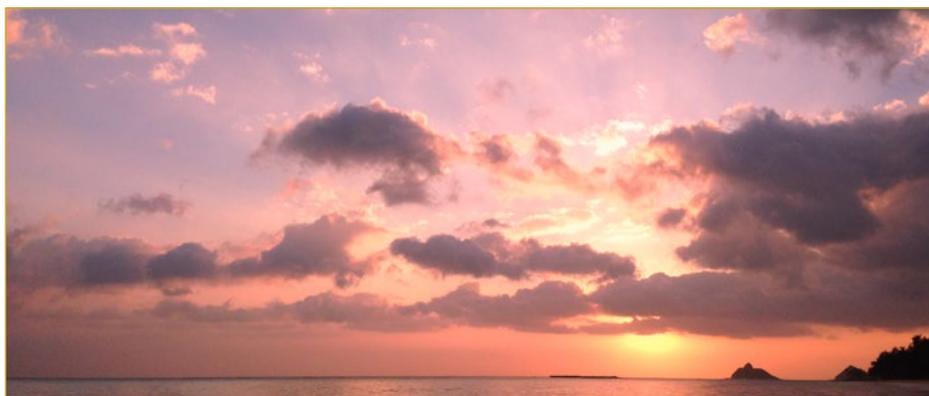
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