



# NEWSLETTER

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## Updates and Events

ORI is hosting and co-hosting a number of events in 2016, which will be of interest to Research Integrity Officers and others interested in research integrity, misconduct, and the responsible conduct of research. Be sure to check out p. 4, bookmark our website, and follow us on Twitter to get all the most recent information and updates.

<http://ori.hhs.gov> 

@HHS\_ORI 

<http://ori.hhs.gov/email-subscribe> 

## Message from the Director



**I**n science, it is all about communication. Research is performed by teams, and the quality of the hypothesis, experimental design, execution and interpretation is dependent on accurate and timely communication. Similarly, the work that ORI does with the research community to protect the integrity of biomedical research requires accurate and timely communication.

In my first three months at ORI, my primary goal has been to listen to people. Internally, I have been meeting with ORI and OASH personnel, past and present, to learn about their work and their concerns. I am impressed by the knowledge and expertise of the people I have met. Most significantly, I am impressed with their ideas about how ORI could evolve in the upcoming years: these are ambitious and worthy ideas.

I have also been listening to key stakeholders in the research community, including Research Integrity Officers, RCR instructors, and Institutional Officials from many different institutions. I am listening to other PHS entities, as well as non-PHS federal entities that are engaged in biomedical research. I am listening to professional societies with memberships that are engaged in research, publishing, and research administration. I have found people to be incredibly generous with their time and talent. The experience has been extremely rewarding.

I hope to have concluded the “listening tour” by late May, and will tell you what I am hearing. We will then use these discussions as an impetus for the strategic growth of ORI. If you have ideas you want to communicate with me, I encourage you to send an email to [askORI@hhs.gov](mailto:askORI@hhs.gov) and share your thoughts. The quality of the strategic planning in ORI is critically dependent on communication – please join in the conversation if you have not yet had an opportunity to do so.

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### Job Opportunities at ORI

ORI is currently looking for talented researchers and subject matter experts who could contribute to our teams. Job announcements will be posted on [USAjobs.gov](http://USAjobs.gov) and will also be announced on our website (<http://ori.hhs.gov>).

## Research Integrity in Asia and the Pacific Rim

### Meeting Summary

A group of 63 representatives from 12 Asia-Pacific Rim countries gathered in San Diego, California on February 24-26 to examine country-specific guidelines, policies, regulatory frameworks for handling research misconduct investigations and promoting integrity. The group consisted of research integrity officers, institutional administrators, and government officials, focused on fostering the responsible conduct of research and instituting processes for addressing research misconduct allegations.

At the conference, attendees joined the newly formed Asia-Pacific Research Integrity (APRI) network, which was established in 2015. Attendees are communicating to determine next steps for the network, including a future meeting.

### Evaluation of the Meeting

Attendees were asked to complete a simple questionnaire after each session. Evaluations were collected from 60% of attendees, representing eight countries (and eight participants whose country was unknown).

Responses indicate that 100% of attendees agreed that they now have a better understanding of the goals and role of the APRI network and are interested in becoming more involved. Of those who completed the evaluation, 100% agree they now have a better overall understanding of U.S. rules and regulations and 97% agreed that they are now more confident in their ability to comply with U.S. regulations in the future. Lastly, 100% of respondents said they gained skills that will help them do their job better and will seek advice or collaborate with someone they met at the meeting.

**February 24-26, 2016 — San Diego, CA**

**Co-Sponsored by:** University of California – San Diego and the Office of Research Integrity

**Countries represented:** Australia, Canada, China & Hong Kong, India, Japan, New Zealand, Pakistan, Singapore, South Korea, Taiwan, Thailand, and the U.S.

**Meeting attendees:** 63

### Key Quotes from Meeting Evaluations

*“The APRI meeting enabled me and my institution to build a greater understanding of research cultures in the US and Asia, and enabled me and my institution to build trust, friendship and a collaborative research project into understanding research integrity environments with Korea.”*

*“Meeting was well attended and gave a chance to everyone to express views freely and understand specific problems that exist in various different countries and we are able to learn from each other’s experience. Over all, the meeting was well conducted and gave birth to APRI.”*

*“It was just fantastic. Made many friends, contacts, and learned more information about the complex process of research integrity.”*

## Conferences and Workshops

In addition to our ongoing Research Integrity Officer (RIO) Boot Camps, upcoming events will focus on research integrity conferences that are sponsored by ORI through its grant program (p. 7, this volume).

### ORI Conference and Workshop Program

#### Promoting the Responsible Conduct of Research for College and University Leaders

Los Angeles, CA Co-Sponsored with Loyola Marymount University

April 14–16, 2016

ORI and Loyola Marymount University (LMU) are Co-sponsoring a meeting for university leaders from diverse institutions around the country. This inaugural meeting will bring together representatives from NIH, NSF, OLAW, OHRP and ORI with senior institutional officials and Research Integrity Officers. Attendees will engage in discussion and develop a greater understanding around promoting research integrity at the highest institutional level. We hope this will serve as a model for future gatherings.

Dr. John Carfora, LMU's Associate Provost for Research Advancement and Compliance, says, "There needs to be greater and more substantive effort put into the teaching and incentivizing of research integrity, the Responsible Conduct of Research (RCR), and the ethical conduct of scholarly activity in general at the highest levels of education. In my opinion, this inaugural meeting on Promoting the Responsible Conduct of Research for College and University Leaders is definitely a step toward meeting that vision."

### Community Conferences of Interest

#### Sequestration Analysis: Collaborative Institutional Approaches & White Collar Concerns

Indianapolis, IN, sponsored by Indiana University

March 30–April 1, 2016

In academia the sequestration process is vital to conducting a successful analysis of an allegation of research misconduct. Indiana University's goal is to enhance the research integrity community's understanding of the importance and effects of the role of sequestration in research misconduct allegations through a multi-disciplinary approach

involving national subject matter experts. Individual presenters include IT forensic specialists, general counsel and legal representatives, research integrity officers and staff, compliance and safety personnel, campus security, and counseling services. The goal is to provide practical tools and resources to successfully implement what is learned from this innovative and interactive conference. The outcomes may include a checklist to be disseminated to the research integrity community, along with video vignettes to further illustrate the importance and ramifications of effective versus ineffective sequestrations.



@HHS\_ORI

Do you want to get the latest information from ORI? Follow us on Twitter (@HHS\_ORI). Read some recent tweets below:



The screenshot shows a Twitter feed for the account @HHS\_ORI. The tweets are as follows:

- Pinned Tweet:** Research Integrity @HHS\_ORI · Apr 1. Apply by April 15 for research on research integrity grant [go.usa.gov/cESY5](http://go.usa.gov/cESY5), April 22 for a conference grant [go.usa.gov/cESYJ](http://go.usa.gov/cESYJ)!
- Research Integrity @HHS\_ORI · 20h. Are you a #PhD adviser? Might be one someday? This #mentor wants you to learn from her mistakes: [ow.ly/10gEoa](http://ow.ly/10gEoa) @guardian #phdchat
- In reply to Liz Wager. Research Integrity @HHS\_ORI · 23h. Yes, more research is needed!! Know anyone up to the task @SideviewLiz @UKRIO? Shameless Plug for our research FOA: [go.usa.gov/cESY5](http://go.usa.gov/cESY5)
- Research Integrity Retweeted. Liz Wager @SideviewLiz · Apr 4. @HHS\_ORI @UKRIO You might be interested in our systematic review about research integrity. Published today at [onlinelibrary.wiley.com/doi/10.1002/14...](http://onlinelibrary.wiley.com/doi/10.1002/14...)
- Research Integrity @HHS\_ORI · Apr 4. How do you read scientific papers? @ScienceCareer asked #scientists for their tips and tricks #scholarlypublishing [ow.ly/10gzZn](http://ow.ly/10gzZn)
- Research Integrity @HHS\_ORI · Apr 1. Should research misconduct result in jail time? New article from @washingtonpost: [ow.ly/10bWSK](http://ow.ly/10bWSK)



## Federal Update at 2015 Association for Research Integrity Officers (ARIO) Meeting

Dr. Susan Garfinkel, Director of the Division of Investigative Oversight (DIO), gave members an update and fielded questions about trends and practices with an audience of about 100 RIOs and their staff at the annual ARIO meeting, held in Denver, CO. The 3rd annual Association ARIO 2015 Conference was co-hosted by Colorado State University, the University of Colorado, and the University of Wyoming. The meeting took place Sept. 28th-30th with over 100 RIOs and general counsel in attendance. In addition to updates from ORI and the NSF OIG, sessions topics included forensic analysis, the recklessness standard, problems with reproducibility, many practical research misconduct issues, and perspectives from journal editors. The conference included a supplemental hands-on forensic workshop in which participants explored a variety of free image analysis tools. ARIO 2016 will be hosted by Memorial Sloan Kettering Cancer Center from Sept. 26-28 in New York City.



Steering Committee member, Lauran Qualkanbush said, "The ARIO steering committee is working to formalize the association through incorporation and is planning for a membership structure to be announced in 2016. Our vision is to facilitate communication among members including access to a listserv for sharing resources and networking. In addition, ARIO expects the regional groups to become more active, providing local resources, as well as hosting conference calls and regional meetings. We are excited about the upcoming changes and believe that ARIO will continue to grow as a valuable resource and community for RIOs and their general counsel."

For more information, please contact:

### **Lauran Qualkanbush**

Director, Office of Research Integrity  
Northwestern University  
lhaney@northwestern.edu

## IRB-RIO Conference Co-Sponsored by OHRP & Georgetown University — June 2015

A group of research integrity officers (RIOs), institutional review board (IRB) members, and government officials convened in Washington, D.C. June 18-19 to tackle a set of challenges specific to research misconduct investigations in clinical research. RIOs and IRB members from institutions around the country shared their experiences, organizational structures, and suggestions throughout the one-and-a-half day conference, which aimed to illuminate a series of that attendees could feasibly implement in their organizations. Attendees split into three sub-groups that focused on pressing topics in research misconduct: the research misconduct investigation process in clinical research and improving coordination among IRBs and RIOs, guidelines for sequestration and data integrity unique to clinical research, and confidentiality and notification processes. The group of 57 then reconvened and reported potential actionable outcomes for each topic area, detailed below.

### ➤ **Process and Coordination**

- Priorities around regulatory flexibility
- Developing checklists
- Analyzing different models of collaboration between IRB and RIO

### ➤ **Sequestration and Data Integrity**

- Regulatory requirement to sequester prior to/during notifications
- Sequestration of data/devices at other institutions
- Sequestration timing with notification
- Checklists for sequestration

### ➤ **Confidentiality and Disclosure**

Model new policy: An institution's decision to disclose information about an ongoing misconduct case should be calibrated to likelihood of harm to others; there should be a core of information that should represent the minimum requirements for disclosure; need to consider protection of federal funds and human subjects. ORI will continue to work with its partners to further develop resources in this area.



## Japan Agency for Medical Research & Development Visits

During September 2015 ORI Division Directors and Fellows met with Miki Horiuchi, JD, DDS, and Naoko Akimoto, JD, PhD, to discuss research integrity. The Japan Agency for Medical Research and Development aims to act as a “control tower” that directs integrated research, from basic research to practical application in Japan.

## ORI Highlights Training Materials for Peer Review Week

The first ever Peer Review Week (<http://exchanges.wiley.com/blog/2015/09/10/celebrating-peer-review-announcing-peer-review-week-2015/>), organized by [Wiley](#), [ORCID](#), [Sense about Science](#), and [Science Open](#), took place September 28-October 2, 2015. Activities promoted a lively discussion, particularly on Twitter. Peer review makes up one of the nine core areas of responsible conduct of research (RCR), plays an important role in how science self-corrects, and helps promote integrity in research and the published literature.

ORI has funded a number of online learning tools, reference materials, and case studies on peer review to facilitate RCR instruction:

### Peer Review Modules

- Peer Review chapter from The ORI Casebook (<http://ori.hhs.gov/rcr-casebook-peer-review/>): Stories about Researchers Worth Discussing.
- Chapter Ten (<http://ori.hhs.gov/chapter-10-peer-review-Introduction/>): Peer Review from ORI Introduction to the Responsible Conduct of Research.
- Ethics of Peer Review (<https://ori.hhs.gov/yale-university/>): A Guide for Manuscript Reviewers. Module contains training materials for young scientists and physicians who are new to the peer review process.

- Test Your Knowledge of Peer Review ([https://ori.hhs.gov/education/products/niu\\_peerreview/](https://ori.hhs.gov/education/products/niu_peerreview/)). Explore common mistakes and dilemmas faced by peer reviewers through a variety of activities such as quizzes, games, cases, etc.
- Evaluating Data Analyses During Peer Review (<http://ori.hhs.gov/education/products/PeerReview/>). This web module helps reviewers evaluate the data analysis section of a submission. The tool includes information on univariate and multivariate logistic regression, linear regression models, factorial analysis of variance, analysis of covariance, repeated analysis of variance, and multivariate analysis of variance.

### Case Studies from the RCR Casebook: Stories about Researchers Worth Discussing

- Pandering to the Public (<http://ori.hhs.gov/case-one-pandering-public/>)
- Getting a Fair Shake (<http://ori.hhs.gov/case-two-getting-fair-shake/>)
- Getting Scooped by a Reviewer (<http://ori.hhs.gov/case-three-getting-scooped-reviewer/>)
- Mysteriously Similar Articles (Role Play) (<http://ori.hhs.gov/role-play-mysteriously-similar-articles/>)

**Responsible Authorship and Peer Review** ([http://ccnmtl.columbia.edu/projects/rcr/rcr\\_authorship/](http://ccnmtl.columbia.edu/projects/rcr/rcr_authorship/)): A training module created by Columbia University that includes three case studies with Q&A discussion guides, annotations, background texts, and annotated resources.

## Extramural Research Program



### 2016 FOAs for Research on Research Integrity Program

These funding mechanisms support research grants and conferences in FY2016

#### 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) has changed 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. **Importantly, this announcement adds a fourth category:** research to develop tools that can be used by Research Integrity Officers (RIOs) at Public Health Service (PHS)-funded institutions to more efficiently detect and analyze falsification and/or fabrication of images and quantitative data. The research program is structured in two phases. **The deadline for submitting a Phase I application is April 15, 2016; Phase II and conference applications are due April 22.**

**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 \$100,000 for a period of one year. Up to ten Phase I projects will be funded. For the first phase, ORI is seeking small-scale, developmental research projects that must have the following characteristics:

1) The research is either: a) discipline-specific or cross-disciplinary and arises out of the theoretical and empirical literature of social science and related disciplines seeking to understand behavior in a social context: anthropology, economics, sociology, criminology

(specifically white collar crime), psychology (particularly social and cognitive) and law; or b) arises out of disciplines such as mathematics, statistics, engineering, computer science, and artificial intelligence and focuses on the technical aspects (e.g., image forensics, statistical forensics) required to develop state-of-the-art tools for detecting falsification and/or fabrication of images and data; and

2) The project includes collaboration with institutional research misconduct officials and/or others who have direct experience with 42 CFR Part 93, including institutional attorneys experienced with institutional research misconduct proceedings; and

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## Extramural Research Program

### ORI Funds Seven Grants on Research Integrity in 2015

ORI is pleased to have awarded two research grants and five conference grants through our Research on Research Integrity program.

#### Phase I Research on Research Integrity Awardees

##### *Perceptions of Scientific Misconduct in the Natural and Social Sciences*

**Kristy Holtfreter, PhD**  
**Arizona State University**

**Abstract:** This study will contribute to the body of knowledge regarding scholars' perceptions of scientific misconduct. Specifically, the proposed study will assess scholars' perceived frequency of a full range of forms of scientific misconduct, including fabricating research findings, falsifying research findings, plagiarism, and authorship fraud, as well as forms of resource mismanagement. Scholars' perceptions of the seriousness of these forms of scientific misconduct (i.e., independent of their prevalence) will also be examined.

**Objectives:** The project will generate a sample of PhD-level researchers from American universities, both from the natural and social sciences. Investigators will develop scientific misconduct measures with strong construct validity and will assess scholars' perceptions of the prevalence and severity of scientific misconduct in a multivariate context. These analyses will entail examining variables drawn from a number of criminological theories that have been empirically shown to be predictive of various forms of misbehavior, including unethical and fraudulent behavior.

**Outcomes:** The study will produce an exhaustive list of survey items that will be made available in the investigators' publications that future researchers working in this area can conveniently access. It will also contribute to the understanding of scientific misconduct by developing survey items that reflect a form of misconduct (i.e., resource mismanagement) that has yet to be empirically investigated. Finally, the development of an empirically-validated set of scientific misconduct measures will signify a clear and meaningful contribution to the research literature in this substantive area.

**Products:** In addition to the final report required by ORI, the data obtained for this project will be used to produce several high-quality conference papers (e.g.,

presentations will be delivered at the American Society of Criminology annual meeting) and multiple peer-reviewed publications in scientific journals of general interest (e.g., *Science*). Study results will be disseminated to the general public via the media and shared electronically.

##### *Bioethical Issues in Biostatistical Consulting (BIBC): A Phase I Study*

**Min-Qi Wang, PhD**  
**University of Maryland College Park**

**Abstract:** The overall purpose of this proposed one-year study, conducted in collaboration with the American Statistical Association (ASA), is to investigate — for the first time — the frequency and relative severity of a broad array of bioethical violations requests that are presented to US biostatisticians by investigators seeking biostatistical consults. A 35-item Bioethical Issues in Biostatistical Consulting Questionnaire (BIBC Q), developed, construct validated and pretested within an NIH/NIDR-funded Oral Health Disparities Center (U54 DE14257-08), along with a short Demographic Data Form (DDF), will be administered to a random sample of US biostatisticians, data analysts and researchers. The proposed Phase I study's specific aims are: 1) to establish the frequency of occurrence (i.e., prevalence) of requests to US biostatisticians for 35 pre-established biostatistical consulting and data analysis practices that are in violation of bioethical standards; 2) to determine the relative severity level for each of those 35 pre-established bioethical violations; 3) to explore the patterns of responses to the bioethical violations questions across strata of investigator characteristics obtained via the Demographic Data Form (DDF); 4) to qualitatively assess the impact that any observed bioethical violation would have on research and on perception of research integrity; and 5) to inform investigators, biostatisticians and biethicists, as well as the regulators of this system (Institute Review Board: IRBs) and trainers of future investigators of the findings from this first exploratory study so they can know 'the facts' and — if needed —



## Extramural Research Program (cont'd)

can modify behaviors and educational approaches to address identified areas of deviation from integrity in research. Based on the Phase I findings, Phase II

will further investigate the reasons for these bioethical violations and why the statisticians are not reporting misconduct.

### Research Conferences on Research Integrity

#### *Keeping the Pool Clean: Prevention and Management of Misconduct Related Retractions*

**Carolyn Broccardo, PhD**  
Colorado State University

**Abstract:** The goal of this conference is to provide a mechanism for collaboration and communication for the diverse set of individuals involved in research misconduct investigations and subsequent retractions. These investigations may be triggered by information shared by journal editors, co-authors, researchers, and anonymous whistleblowers. The outcome of this effort is often retraction of published manuscripts, which lacks in uniformity and rigor, and policies vary from clear to nonexistent depending on the institution and journal. The objective of this conference two-fold: 1) provide a forum to discuss the problem of retractions and address the tension and competing interests between those involved in misconduct related retractions, and 2) create a diverse interdisciplinary collaboration capable of generating a guidance document and best practices for those involved in misconduct investigations and related retractions. Specifically, guidance shall be on key issues related to misconduct-related retractions including: identification, communication, ethics, reporting to institution/government, retraction notices, database management, and other issues deemed relevant by session participants. The final product will be shared nationally and internationally, through a peer reviewed publication.

#### *It Happens to Everyone: PUI Research Integrity and Responsible Conduct of Research*

**Joann Waite, PhD**  
Gonzaga University

**Abstract:** Ethical research training during the undergraduate experience has multiple benefits; it is valuable for the students, the graduate program the student will enter, the researcher the student will work with, and the public who will fund the research. As such, it is crucial to train the faculty, staff, and administration who are the gateway to students who will one day be the PhDs who are expected to perform continued ethical research throughout their research, professional, and

scholarly careers. Titus et al. wrote, "an analysis commissioned by the ORI found in 2000 that only 29% of institutional misconduct polices explicitly obligate members to report scientific misconduct. Individuals and institutions, not the federal government, are the guardians of research integrity. Therefore, we urge action and recommend six strategies to champion integrity." The six recommendations are: adopt zero tolerance, protect whistleblowers, clarify how to report, train the mentors, use alternative mechanisms, and model ethical behavior. This proposed conference outcomes will first impact Predominately Undergraduate Institutions (PUIs) across the United States where undergraduate students will be more consistently trained in research integrity processes. In addition, the PUI faculty will have the institutional support of implemented policy and procedures, research data will be readily available and usable for replication and transparency, and faculty and administrators will have a broader understanding of why misconduct happens. Finally, this conference will train a new cohort of research integrity trainers in the critical process of data management.

#### *Sequestration Analysis: Collaborative Institutional Approaches & White Collar Concerns*

**Dr. John Baumann**  
Indiana University

**Abstract:** ORI has reiterated through several workshops and conferences, and it is a common discussion topic amongst RIOs and staff throughout our national research community, that the sequestration process is one of the most important and vital steps to building a successful analysis of an allegation of research misconduct. Indiana University's goal is to enhance the research integrity community's understanding of the importance and effects of the role of sequestration in research misconduct allegations while providing practical tools and resources to successfully implement what is learned from this innovative and interactive conference, "Sequestration Analysis: Collaborative Institutional Approaches & White Collar Concerns." This conference proposal includes a multi-disciplinary approach to involve not only national subject matter experts in each relevant area, but also to analyze the entire process

## Extramural Research Program (cont'd)

from every angle so as to include the breadth of individuals such as IT forensic specialists, general counsel and legal representatives, research integrity officers and staff, compliance and safety personnel, campus security, and counseling services that must be involved when completing sequestration. The outcomes will include a best practice guidance document to be disseminated to the research integrity community, along with video vignettes to further illustrate the importance and ramifications of effective versus ineffective sequestrations.

### **Survey Data Fabrication Workshop**

Fritz Scheuren, PhD

National Opinion Research Center at the University of Chicago

**Abstract:** This Workshop is intended to bring the survey community together to share our joint concerns about data fabrication or “curbstoning.” While a very old issue, curbstoning concerns have recently been growing in intensity. There is a widespread fear, supported by anecdotal evidence, that curbstoning may be getting worse. We simply do not know, and that bothers many of us even more. Wholesale fabrication of data can be seen as an attack on the credibility of all we do; hence, in this instance ignorance is not bliss. The workshop format proposed here will allow us to listen to other survey practitioners who have begun, like us, to address the dangerous fabrication concerns facing everyone in the survey industry. There are recent advances to discuss,

many by us, some by others in fabrication prevention, fabrication detection and even in the repair of surveys where data have been found or thought to be fabricated. Since fabrication is a prey/predator problem it requires a process not just a product response. It is a virus ever-adapting; hence, to combat it we need to adapt, too. Our main workshop goal, therefore, is to move the survey research community toward a forward-looking, iterative process for continuously countering what sadly will be never ever ending concerns about curbstoning.

### **Research Integrity and Sensitive Populations: Best Practices for Responsible Conduct in Social Sciences Research, Gulf Coast Conference**

Dr. Carla Thompson

University of West Florida

**Abstract:** Although Institutional Review Boards provide special clearly defined responsible conduct for the protection and welfare of vulnerable populations (such as children and minors, elderly and aging, cognitively impaired persons, ethnic minorities, prisoners, women, and others) in medical and clinical research efforts as required by federal regulations [45 CFR 46], appropriate attention to sensitive groups relative to responsible conduct and prevention of misconduct within social science research efforts has not been a strong clear focus of institutional review boards in higher education settings. Also, new sensitive research efforts, such as sports participation in schools, gender orientations, and

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## The RIO's Corner

### Three Things RIOs and Their Institutional Counsel Should Remember

- 1 **“Effective sequestration can strengthen your findings”**  
Sequestering early, casting a very wide net, and being sure that you have the best cataloging of the evidence possible, can facilitate the use of objective evidence to strongly support or refute an allegation.
- 2 **“Don't wait to call ORI”**  
Although institutions have a requirement to notify ORI when it is determined that an Investigation of PHS-funded research is warranted, they are welcome to call any time prior to that. ORI scientist-investigators are available to answer questions at any time during an assessment, inquiry, or investigation. Contact AskORI@hhs.gov.
- 3 **“Effective RCR instruction may prevent misconduct”**  
Inappropriate manipulation of images or selection of data can lead to a finding of misconduct. Effective RCR instruction can provide researchers and trainees with the tools they need to handle data and images with integrity. Effective communication between RIOs and RCR instructors is beneficial. ORI has RCR resources to assist you on our website.

The RIO's 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.

## New NIH Policy on Data Will Affect PHS-Funded Research

A new policy became effective on January 25, 2016, that should help the research community enhance the integrity of biomedical research.

Scientists are expected to know how to select data, analyze data, and interpret data — with integrity. However, the access to RCR training across subdisciplines often varies, leading trainees to believe that “massaging” data (inappropriate data selection) to support a specific hypothesis is a common and acceptable practice. Unfortunately, those very assumptions could lead a trainee to manipulate data in a manner not acceptable to the research community, therefore drawing into question the validity of the results being reported.

The National Institutes of Health (NIH) has published an important new [policy](#) that should help researchers understand what is expected of them and give them specific guidance on how to comply. NIH study sections will “focus on four areas deemed important for enhancing rigor and transparency: 1) the scientific premise of the proposed research, 2) rigorous experimental design for robust and unbiased results, 3) consideration of relevant biological variables, and 4) authentication of key biological and/or chemical resources.” NIH has published a [new website](#) on rigor and reproducibility, as well as a [new FAQ](#) site, both of which contain useful information for researchers who expect to submit grants for PHS funding.

Researchers will need to read the revised grant application instructions that will be incorporated into the SF424 (Research and Related) Application Guide. Let’s take a closer look at the “scientific premise” component of the new policy, which will be a component of the “Significance” section of the grant. It is important that the proposal includes an objective assessment of the integrity of literature cited within this section. The assessment should include the reliability of the cited research, by specifically addressing aspects of that research including the statistical power of the cited research, whether the data include both males and females if animal models were used, whether critical reagents have the appropriate validation or authentication, and whether the researchers were appropriately blinded during the data

acquisition. Weaknesses of the experimental design of literature cited to emphasize the significance of the proposed research must be delineated, and then improved in the experimental design of the proposed research. This will allow reviewers to ascertain if the methodology planned is appropriate. The second focus area is “rigorous experimental design” which will require applicants to address in their experimental methods how experiments are controlled and therefore results are better able to be reproduced. Specific examples may include such attributes of the design as sample size, power, confidence levels, acquisition intervals, positive and negative controls, researcher masking/blinding, and sample handling. Specific criteria for sample inclusion and exclusion will make datasets more robust and more readily reproducible. Again, for the trainee, a deep understanding of selection criteria that are imposed prior to seeing the actual data will be instructive.

The new requirements from NIH for grant applications and review criteria may be intended to ensure that it funds the best and most rigorous science. However, increased scrutiny of published data may also have consequences for potential research misconduct, since it may make it more difficult for a researcher to publish fabricated data or to publish falsified results that are based on the omission of data that provides a desired result.

We applaud the efforts of the many groups and individuals who have contributed to this important effort underway at NIH. As the research community works diligently to address concerns of lack of reproducibility in some preclinical animal models, so can they reduce the risk that inappropriate manipulation of data and improve the integrity and reproducibility of their research.

### Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications

**Notice Number:** NOT-OD-16-012

#### Key Dates

**Release Date:** October 13, 2015

## ORI Perspective on Global Misconduct

DIO continues to handle allegations of research misconduct sent directly to ORI or through institutions already involved in research misconduct proceedings. Several of these allegations involve PHS-supported research conducted at non-US institutions or performed in the US by non-US researchers who have already returned to their home countries. Further, several major news stories recently hit the press about research mis-

conduct globally, specifically in Asia. ORI coordinated with our colleagues at the University of California, San Francisco (UCSF) to co-sponsor a two-day planning meeting with representatives from institutions in China, Japan, South Korea, Hong Kong, Taiwan, Thailand, India, Australia, and New Zealand to discuss relevant issues, set an agenda and to identify speakers and attendees for ORI's "Research Integrity in Asia and the Pacific Rim" conference February, 2016.

## A Call to Develop Mentors for International Research

Article reviewed by Sandra Titus, PhD

How many universities prepare their graduate students and post-doctoral candidates for a role in international collaborations? How many programs have continuing educational programs for senior faculty who want to be involved internationally and pass their knowledge and values on to the next generation of scientists? In their recent paper, Cordova, Furukawa, and Yaghi argue that mentoring on a global scale is essential to accelerate knowledge and development of science and research.

This team of researchers writes ardently that, "The mentoring relationship is the golden thread of innovation that helps to maintain and sustain a vibrant science culture." Based on their own programs (in California, Vietnam, Saudi Arabia, Japan, and Korea) as well as other international mentoring enterprises, they suggest key features and principles featured below that an international mentoring program must take into account in order to build trust as well as develop a successful program. While their article focuses on the development of global centers, it also provides insight on ways that educational RCR programs can consider in order to foster the education in leadership and mentoring.

To enhance international mentoring, they suggest the leader and mentor consider the following:

- 1 Build a culture that is inclusive, especially of minorities and women**
- 2 Develop skills to guide others**
- 3 Engage others in developing mutual understandings**
- 4 Practice being accessible on a routine basis: this may involve traveling, video conferencing and electronic communication**
- 5 Have a clear vision for what the mentoring process entails, and build the infrastructure to support it**
- 6 Ensure the program is sustainable for many years**

This paper urges educators and mentors to consider ways to educate and support the development and preparation for this enhanced and emerging leadership mentoring role.

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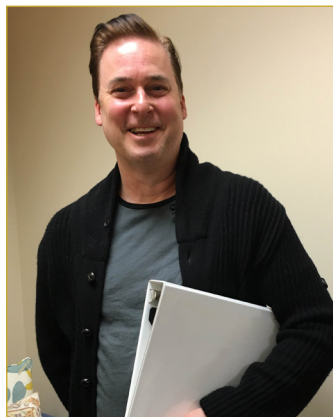
Cordova, KE, Furukawa, H, and Yaghi, OM. The development of global science (2015). "Development of Global Science," ACS Cent Sci, 1, 18-23 DOI:10.1021.acscentsci.5b00028

## Meet ORI's Newest Staff

### Meet Anthony LeFevour

The Division of Education and Integrity (DEI) is pleased to introduce its newest employee, **Anthony LeFevour**, to serve as Staff Assistant to Division Director Zoë Hammatt. Anthony, who started at ORI in December, 2015, comes to the Office with a deep passion for ORI's mission and with extensive professional experience in research.

Anthony comes from a family that values education in America — his father was a college president, and his mother was a teacher. Anthony earned his undergraduate degree at Hobart & William Smith Colleges, in Japanese Economic History, and his MA at Boston University in Brain, Behavior and Cognition. He performed post-graduate research on Alzheimers disease and its prevention. Anthony then spent several years working in a clinical mental health setting in Oregon. He returned to the East Coast and continued his research career at both the National Institutes of Health and the Centers for Disease Control. Anthony has a deep understanding of basic and clinical research that, with his professional experiences, will serve as a solid foundation for his job duties at ORI.



**Anthony LeFevour**

DEI is responsible for implementing the educational and prevention missions of ORI. "I like the mission!" Anthony said. During his research career he was able to experience firsthand the pressures to publish in top tier journals and the ethical decision-making that researchers must do in order to conduct research with integrity. Anthony thinks Talmudic wisdom addresses an important aspect of research misconduct in encouraging people to not "tempt others to do wrong."

Anthony has been a great addition to ORI, and we are enjoying having him on board!

### Meet Our ORISE Fellows

Over the past year, ORI has gained two new Oak Ridge Institute for Science and Education (ORISE) fellows. **Madeline Rooney** and **Penelope Theodorou** have

brought energy and enthusiasm to our office since joining the Division of Education & Integrity (DEI) in December 2014 and June 2015, respectively. Both Fellows are recent Master of Public Health (MPH) graduates, and they are leveraging their behavioral research backgrounds and social media savvy to create innovative education and communication initiatives. They are working hard to increase our accessibility and participation in conversations within the research community, particularly through Twitter (@HHS\_ORI), ORI's blog, and other digital media. Penelope and Madeline are also working on a series of papers for publication that examine how public health theories could be used as a framework to research the behavior of misconduct, plan interventions, or increase whistleblowing.



**Penelope Theodorou**



**Madeline Rooney**

Madeline has a BA in Neuroscience and Behavior from Vassar College and worked in a molecular neuroscience lab at the Rockefeller University for two years after graduation. She then attended Johns Hopkins Bloomberg School of Public Health, where she earned her MPH in Social and Behavioral Science and Health Communication. Between graduate school and joining ORI, Madeline spent five months in Uganda as an intern at UNICEF, where she worked on a mobile communications and data collection project. Outside the office, Maddie enjoys playing on a co-ed floor hockey team, eating her way through DC, and exploring the



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## Inside ORI - Behind the Scenes

## Spotlight on Robin Parker, Assurance Program Specialist

One phone call could transport Robin Parker to India in seconds. From the confines of her seventh-floor office in Rockville, MD, she's been to Africa, China, and the United Kingdom – and she has no idea where she's going next.

In her role as Assurance Program Specialist at ORI, Parker has connected with 342 foreign institutions to ensure compliance with Public Health Service regulations. As an essential contact for these institutions, combined with an additional 5,700 contacts in the US alone, Parker has become a master of dialects, databases, and deadlines.

Parker documents institutions' compliance with two federal requirements: submitting an annual report on research misconduct and establishing policies and procedures for handling allegations of research misconduct. In some cases, she places holds on funding when institutions fail to meet deadlines for submitting documentation.

"I really enjoy what I do, because I touch so many peoples' lives," she said. "I communicate with people from all ethnicities, and it's been a pleasure, because I've never had any bad encounters."

We sat down with Robin to discuss her experience at ORI.

**How long have you been working at ORI, and how long have you been overseeing the assurance program?**

**Robin:** I started working at ORI in September of 1995 as a Secretary, but was then promoted to Program



Assistant. I became the Assurance Program Specialist in June of 2007.

**Can you describe the Assurance Program and your role as Assurance Program Specialist?**

**Robin:** When an institution applies through NIH for Public Health Service (PHS)-funded research, NIH reviews their application to ensure that the institution meets all requirements. Once that institution meets NIH requirements, NIH sends the information over to our office, and we create an assurance record.

*"I really enjoy what I do, because I touch so many people's lives. I communicate with people from all ethnicities, and it's been a pleasure, because I've never had any bad encounters."*

— Robin Parker

There are approximately 5,000 active institutions that apply for PHS-funded research grants. We maintain those records to ensure that each institution is compliant with the PHS Federal Regulation,

42 CFR Part 93. For the assurance program there are two requirements from the institutions. First, institutions are required to complete an annual report on possible research misconduct. The institutions report any allegations that fall under the PHS regulation: falsification, fabrication, and plagiarism. If there is a determination to move to an institutional Investigation, they notify the Division of Investigative Oversight (DIO).

The second requirement is for [institutions] to have a policy and procedure to respond to allegations of research misconduct, which must comply with 42 CFR Part 93. We have a checklist that we have developed for the institutions to assist them in being compliant.

I work with the Grants Management Specialist at PHS funding agencies and with the institutional signing officials who assist institutions in maintaining their assurance record with their reports and policies.

**So you're responsible for coordination between several different entities involved in PHS-funded research.**

**Robin:** Yes—the grants management specialist at PHS funding agencies and the institutional signing officials to make sure that they get their reports in before the deadline, which is April 30th. The electronic submission date starts January 1, and the deadline date is April 30th. I assist in getting the report in on time, because if they do not comply, their funds are put on hold. I contact NIH and say, "These

## Inside ORI - Behind the Scenes (cont'd)

institutions are late with their report—please hold transactions on their accounts or records.”

**Your role is unique in that you get to communicate with a lot of different international entities.**

**Robin:** I was kind of shy when I first started as the Assurance Program Specialist, but talking to as many people as I do, as the years have gone by, I've become very comfortable. A lot of them have not ever met me in person, but through telephone contact, I communicate with people from all ethnicities. I deal with a lot of people — institutional signing officials from over 5,000 records — and a number of these people may need to call me, email me, or send faxes. So, I'm dealing with the grants management specialist and I'm dealing with the institutional signing officials to make sure that certified officials are meeting their requirements.

**It's kind of like you're traveling around the world from your desk.**

**Robin:** Exactly! I get calls from individuals in India, but in the same day I could get a call from someone in China, or I could get a call from someone in Africa. I have to listen very closely to their needs in order to properly assist them. It's been rewarding. I've had people say, “Hey, it's good talking to you... you have a very soothing voice.

Thank you so much for your help.” I get a lot of comments saying callers appreciate us being there, answering the phone, and providing immediate assistance. So it's been rewarding.

**You deal with a lot of paperwork. How has technology changed processes within the Assurance program?**

**Robin:** When I first started here, the Assurance program was performed manually, meaning that I was a part of stuffing envelopes, mailing the reports out, and opening the envelopes when they came back in. We handled everything manually. I was first offered this job when the former specialist retired, and I didn't want to take the job because I said, “That is too much.” Looking at his desk, he had paperwork all over the place...but now it's so much easier. The ORI database has automated our processes, and we communicate electronically with the NIH database as well.

**Are there times when you have an influx of people contacting you — does it vary throughout the year?**

**Robin:** It goes up and down. January 1 through April 30 is the busiest time because the institutions are submitting their electronic annual report submissions; submitting their policies and procedures...

When January 1 hits, I can get up to 300 reports in one day because [institutions] want to get their information in.

**Organization and attention-to-detail seem pretty essential for this position.**

**Robin:** Very much. I didn't know I had it in me. Multi-tasking is essential; I could be answering email, then a phone call may come through, and I may have to jump from the email to answer the phone call. Then I may have to jump from the phone call to check the database, then from our database to the NIH database. Telephone calls, emails, faxes.

It's been very rewarding to work in this office, and I've enjoyed working in this office. It's one of the best places I've ever worked — learning about the research and research grants has been really interesting. It's been a learning experience for me.

**What do you do for fun outside ORI?**

**Robin:** I enjoy spending time with my family. Most of my time is spent with my husband and grandchildren. I'm also known as Reverend Robin Parker at my church, where I volunteer my time and participate in many activities.

## 2016 FOAs for Research on Research Integrity Program

*continued from page 7*

3) The project takes place in research settings and/or includes individuals actively engaged in or training for careers in research.

**Phase II:** Phase II constitutes 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 \$175,000 per year (direct).

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

### Conference Grants

The RRI Program will also grant awards for conferences. The funding will provide opportunities for applicants to hold meetings on research integrity issues at various locations across the United States. The conference grant program aims to promote the expansion of the re-

search 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 has been posted on Grants.gov, the ORI website, Twitter (@HHS\_ORI), and via e-mail update (<http://ori.hhs.gov/email-subscribe>).

## ORI Funds Seven Grants on Research Integrity in 2015

*continued from page 10*

caregiving for aging populations are examples of emerging sensitive populations research arenas. The proposed conference will focus on research integrity and sensitive populations' research within the context of social science research conducted in higher education settings. The proposed two-day face-to-face conference with an extended online follow-up convening effort will bring together an interdisciplinary group of higher education faculty, researchers, national experts, regional community leaders, and

graduate students who represent specific aspects of social science research focused on sensitive topics and sensitive populations. The purpose of the proposed Sprint Gulf Coast Conference is to promote research integrity and prevent research misconduct by producing three educational/informational deliverables for social science educators/researchers: 1) a protocol for implementing RCR best practices training in social science research with sensitive topics and sensitive populations, including actions and procedures for

dealing with research misconduct and whistleblowing; 2) a digital portal containing FAQs for social science researchers and educators; and 3) dissemination of conference findings at the annual conference of the American Association of Behavioral and Social Sciences Conference (AABSS) and published in the Journal of AABSS. Conference participants will serve as ambassadors for promoting the RCR training specifically focused on research involving sensitive populations and/or sensitive topics.

## Meet Our ORISE Fellows

*continued from page 13*

local parks with her boyfriend and their dog, Lucy.

Penelope earned her BS at the University of Arizona, where she studied Public Health and Psychology. While there, she researched infant

cognitive development and language acquisition. She then attended Emory University's Rollins School of Public Health, where she completed an MPH in Behavioral Sciences and Health Education, with a certificate in Maternal and Child Health. Outside

the office, Penelope enjoys spending time with her big Greek family, especially her new nephew. She is a cooking aficionado who enjoys discovering new recipes and sharing her creations with her colleagues.



## Case Summaries of Research Misconduct Findings

### Bijan Ahvazi, PhD National Institutes of Health

Based on the report of an investigation conducted by the National Institutes of Health (NIH) and additional analysis by ORI in its oversight review, ORI found that Dr. Bijan Ahvazi, former Director of the Laboratory of X-ray Crystallography, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NIH, engaged in research misconduct in research supported by the Intramural Program at NIAMS, NIH.

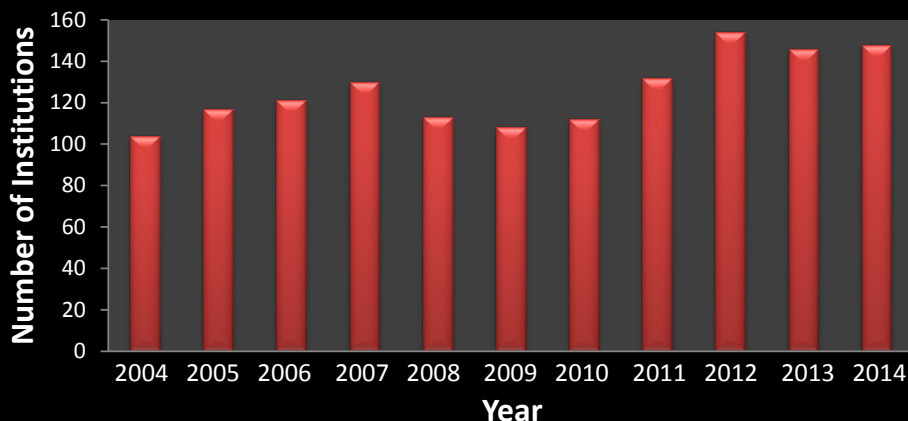
ORI found that Respondent engaged in research misconduct by falsifying data related to or in the following published papers:

1. Ahvazi, B., Boeshans, K.M., Idler, W., Baxa, U., & Steinert, P.M. "Structural basis for the coordinated regulation of transglutaminase 3 by guanine nucleotides and calcium/magnesium." *J. Biol. Chem.* 279(8):7180-92, 2004 Feb 20 (withdrawn) (hereinafter "JBC 2004a")
2. Ahvazi, B., Boeshans, K.M., & Steinert, P.M. "Crystal structure of transglutaminase 3 in complex with BMP: Structural basis for nucleotide specificity." *J. Biol. Chem.* 279:26716-25, 2004 (withdrawn) (hereinafter "JBC 2004b")
3. Ahvazi, B., Boeshans, K.M., Idler, W., & Cooper, A.J.L. "Crystal structure of transglutaminase 3-cystamine complex: Binding of two cystamines to the nucleotide-binding pocket. M6:06060, Submitted to *J. Biol. Chem.*, 2006 (rejected) (hereinafter "JBC 2006").

Specifically, ORI finds that Respondent:

1. falsely labeled Figure 3A in JBC 2004b representing an isothermal calorimetric titration (ITC) experiment using guanine monophosphate (GMP) and transglutaminase 3 (TGase 3) when the figure was actually a relabeled version of an unrelated experiment that Respondent previously published as Figure 1A in JBC 2004a.
2. falsified Figure 4B, Figure 4C, and Figure 6D in JBC 2004b and Figure 5E in JBC 2006, by altering the original data in the following ways to represent the desired experiment:
  - a. falsified Figure 4B in JBC 2004b, by adding multiple data points to titration curves for four different concentrations of TGase 3 bound by different concentrations of tagged GTP $\gamma$ S and deleting two (2) outlying data points from one of the curves
  - b. falsified Figure 4C in JBC 2004 b, representing a competition assay for the release of tagged GTP $\gamma$ S bound to

### Number of Institutions Reporting Research Misconduct Activity to ORI (2004-2014)



*Number of institutions that reported research misconduct activity, defined as the handling of allegations, inquiries, and/or investigations that fell within PHS jurisdiction, over the past ten years. These data are collected and tracked by ORI.*

TGase 3, by (1) falsely claiming that the release of the tagged nucleotide occurred with the addition of untagged GMP, when the result was from an assay using untagged GDP, (2) adding additional data points onto the titration curves, and (3) altering the scale of the abscissa

- c. falsified Figure 6D in JBC 2004b, by using the false Figure 4B to also represent an additional competition experiment using unmodified nucleotide analog compounds and ATP; specifically, Respondent (1) falsified the units and labels of the axes, (2) falsified the labels of the curves, and (3) vertically inverted the curves
- d. falsified Figure 5E in the JBC 2006 manuscript, representing a competition experiment for the release of tagged GTP $\gamma$ S bound to TGase 3 with the addition of cystamine, when the actual experiment was a competition experiment with the addition of untagged nucleotides.

Dr. Ahvazi has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on October 7, 2014: (1) to have his US Public Health Service (PHS) research supervised and to notify any employer(s)/institution(s) at which he may participate in PHS funded projects of the terms of his supervision; 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

## Case Summaries of Research Misconduct Findings

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 to work on PHS-supported projects 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.

### **David Anderson** **University of Oregon** **Eugene**

Based on an assessment conducted by the University of Oregon, Eugene (UOE), the Respondent's admission, and analysis conducted by ORI, ORI and UOE found that Mr. David Anderson, Graduate Student, UOE, engaged in research misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grants R01 MH087214 and R01 MH077105.

ORI found that Respondent engaged in research misconduct by falsifying and/or fabricating data in the following four (4) publications:

- Journal of Neuroscience 31(3):1128-38, 2011 (hereafter referred to as "Paper 1")
- Journal of Experimental Psychology: Human Perception and Performance 39(3):824-835, 2012 (hereafter referred to as "Paper 2")
- Attention, Perception and Psychophysics 74(5):891-910, 2012 (hereafter referred to as "Paper 3")
- Psychological Science 24(6):929-38, 2013 (hereafter referred to as "Paper 4")

ORI found that Respondent knowingly falsified data by removing outlier values or replacing outliers with mean values to produce results that conform to predictions. Specifically, these falsifications appear in:

- Figures 4 and 8 in Paper 1
- Figures 3C, 3D, and 3E in Paper 2

- Figures 3B, 7C, 7D, and 8B in Paper 3
- Figures 3E and 3F in Paper 4

Mr. Anderson has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on June 23, 2015: (1) to have his research supervised; Respondent agreed that prior to the submission of an application for US Public Health Service (PHS) support for a research project on which his participation is proposed and prior to his participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of his research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed 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; (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; and (4) to assist UOE in advising publishers of the need to retract or correct the following papers:

- Journal of Neuroscience 31(3):1128-38, 2011
- Journal of Experimental Psychology: Human Perception and Performance 39(3):824-835, 2012
- Attention, Perception and Psychophysics 74(5):891-910, 2012
- Psychological Science 24(6):929-38, 2013

### **Ryan Asherin** **Oregon Health Authority**

Based on the report of an investigation conducted by the Oregon Health Authority (OHA) and analysis conducted by ORI in its oversight review, ORI found that Ryan Asherin, former Surveillance Officer and Principal Investigator, OHA, Public Health Division engaged in research misconduct in research supported by the Centers for Disease Control and Prevention (CDC) Emerging Infections Program Grant 5U01CI00306-05.

ORI found that the Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in the CDC research record, a manuscript submitted to JAMA

## Case Summaries of Research Misconduct Findings

Intern Med in January 2013, a published CDC report (CDC Morbidity and Mortality Weekly Report 61(09):157-162, March 2012), and presentations in 2012 to CDC and at the 11th Biennial Congress of the Anaerobe Society.

ORI found that the Respondent falsified and/or fabricated fifty-six (56) case report forms (CRFs) while acquiring data on the incidence of *Clostridium difficile* infections in Klamath County, Oregon. Specifically, the Respondent (1) fabricated responses to multiple questions on the CRFs for patient demographic data, patient health information, and *Clostridium difficile* infection data, including the diagnoses of toxic megacolon and ileus and the performance of a colectomy, with no evidence in patient medical records to support the responses; and (2) falsified the CRFs by omitting data on the CRFs that clearly were included in patient medical records.

Mr. Asherin has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on May 12, 2015: (1) to have his research supervised; Respondent agrees that prior to submission of an application for US 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 contribution; Respondent agrees that he will 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 must 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.

**Julia Bitzegeio, PhD**  
**Aaron Diamond AIDS Research Center**

Based on the Respondent's admission, an assessment conducted by the Aaron Diamond AIDS Research Center (ADARC), and analysis conducted by ORI in its oversight review, ORI found that Dr. Julia Bitzegeio, former Postdoctoral Fellow, ADARC, engaged in research misconduct in research supported by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), in grants

R01 AI078788, R21 AI093255, and R37 AI064003.

ORI found that Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in one (1) publications, two (2) unfunded grant applications, and one (1) unpublished manuscript:

- Journal of Virology 87:3549-3560, 2013 (hereafter referred to as "JVI 2013")
- R01 AI114367-01A1
- R01 AI120787-01
- "A single amino acid in the CD4 binding site of HIV-1 Env is a key determinant of species tropism." Unpublished manuscript.

Specifically, ORI found that:

1. Respondent falsified and/or fabricated in vitro rates of viral replication or infection in human and macaque lymphocytes and infectious titers on reporter cells, for multiple strains of SIV based chimeric viruses such that the results were not accurately represented in:
  - Figure 7 in JVI 2013
  - Figures 6B and 8C in R01 AI114367-01A1
  - Figures 1, 2B, and 3B in R01 AI120787-01
  - Figures 1A-D, 2D, 3D, 5A-C, 5I, 6C, and S3D in the unpublished manuscript
2. Respondent falsified and/or fabricated in vitro binding data of SIV based chimeric viruses to human or macaque CD4 such that the results were not accurately represented in:
  - Figure 6 in R01 AI120787-01
  - Figures 5D-F in the unpublished manuscript

ADARC has submitted a request for correction of JVI 2013.

Dr. Bitzegeio has entered into a Voluntary Settlement Agreement and has voluntarily agreed:

- (1) that if within three (3) years from the effective date of the Agreement, Respondent receives or applies for U.S. Public Health Service (PHS) support, Respondent agreed to have her research supervised for a period of three (3) years beginning on the date of her employment in a position in which she receives or applies for PHS support and to notify her employer(s)/institution(s) of the terms of this supervision; Respondent agreed that prior to the submission of an application for PHS support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of her duties is submitted

## Case Summaries of Research Misconduct Findings (cont'd)

to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan; (2) that if within three (3) years from the effective date of the Agreement, Respondent receives or applies for PHS support, Respondent agreed that any institution employing her 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 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 for a period of three (3) years, beginning on June 23, 2015.

### **Brandi Blaylock** **University of Wake Forest School of Medicine**

Based on an investigation conducted by Wake Forest School of Medicine (WFSOM) and additional analysis conducted by ORI, ORI found that Ms. Brandi Blaylock, former Graduate Student, WFSOM, engaged in research misconduct in research supported by National Institute of Drug Abuse (NIDA), National Institutes of Health (NIH), grant R01 DA012460 and Ruth L. Kirschstein National Research Service Award (NRSA) K31 DA033106.

ORI found that Respondent engaged in research misconduct by falsifying and/or fabricating data reported in two poster presentations, several laboratory meetings, and progress reports associated with NIDA, NIH, grant R01 DA012460.

Specifically, ORI found that the Respondent knowingly presented falsified and/or fabricated data indicating that twelve non-human primates (either rhesus or cynomolgus monkeys) responded to anti-abuse nicotinic acetylcholine and/or dopamine receptor selective compounds in self-selectivity assays for cocaine, methamphetamines, or nicotine when the compounds were never given to the monkeys per protocol.

Respondent has not applied for or engaged in US Public Health Service (PHS)-supported research within the last three (3) years and has stated that she has no intention of engaging in PHS-supported research in the future.

Ms. Blaylock has entered into a Voluntary Settlement Agreement and has voluntarily agreed:

(1) that if within three (3) years from the effective date of the Agreement, Respondent receives or applies for PHS sup-

port, Respondent agreed to have her research supervised for a period of three (3) years beginning on the date of her employment in a position in which she receives or applies for PHS support and to notify her employer(s)/institution(s) of the terms of this supervision; Respondent agreed that prior to the submission of an application for PHS support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan; (2) that if within three (3) years from the effective date of the Agreement, Respondent receives or applies for PHS support, Respondent agreed that for a period of three (3) years beginning on the date of her employment in a position in which she receives or applies for PHS support, any institution employing her 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 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 for a period of three (3) years, beginning on August 4, 2015.

### **Teresita L. Briones, PhD** **Wayne State University**

Based on the report of an inquiry conducted by Wayne State University (WSU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Teresita L. Briones, former Associate Professor, College of Nursing, WSU, engaged in research misconduct in research supported by National Institute of Nursing Research (NINR), National Institutes of Health (NIH), grants P30 NR009014,

R01 NR005260, and R01 NR007666.

ORI found that Respondent intentionally, knowingly, and recklessly engaged in research misconduct by falsifying and/or fabricating data that were included in five (5) publications and three (3) grant applications submitted to NINR, NIH:

- Behavioural Brain Research 279:112-22, 2015 Feb 15 (hereafter referred to as "BBR 2015")
- Journal of Neuroinflammation 11:13, 2014 Jan 22 (hereafter referred to as "JNI 2014")

## Case Summaries of Research Misconduct Findings (cont'd)

- Journal of Neurotrauma 26(4):613-25, 2009 Apr (hereafter referred to as "JNT 2009")
- Journal of Neurotrauma 28(12):2485-92, 2011 Dec (hereafter referred to as "JNT 2011")
- Neuroscience 262:143-55, 2014 Mar 14 (hereafter referred to as "NS 2014")
- R01 NR011167-01
- R01 NR011167-01A1
- R01 NR 011167-01A2

ORI found that Respondent falsified and/or fabricated data by falsely reporting the results of Western blot experiments that examined neuroinflammation, amyloidogenesis, and/or cognitive impairment in a rat model of cerebral ischemia. Specifically, Respondent duplicated, reused, and falsely relabeled Western blot gel images and claimed they represented different experiments in:

- BBR 2015, Figures 2E and 5D
- JNT 2009, Figures 2B and 5
- JNT 2011, Figure 2
- NS 2014, Figure 4
- R01 NR011167-01, Figures 5 and 6
- R01 NR011167-01A1, Figures 4A and 4B
- R01 NR011167-01A2, Figures 4A and 4B

As a result of this Agreement, Respondent will request that the following publications be retracted: BBR 2015, JNT 2009, JNT 2011, and NS 2014.

Dr. Briones has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on March 12, 2015: (1) to exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' 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 (collectively the "Debarment Regulations"); (2) to exclude herself voluntarily from serving in any advisory capacity to the US Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (3) to request that the following publica-

tions be retracted: BBR 2015, JNT 2009, JNT 2011, and NS 2014.

### **Girija Dasmahapatra, PhD** **Virginia Commonwealth University**

Based on the report of an inquiry conducted by Virginia Commonwealth University (VCU), the willingness of the Respondent to settle this matter, and analysis conducted by ORI in its oversight review, ORI found that Dr. Girija Dasmahapatra, former Instructor, Department of Internal Medicine, VCU, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants R01 CA063753, R01 CA093738, and R01 CA100866.

ORI found that false data were included in the following eleven (11) publications:

- Blood 107:232-40, 2006 Jan (hereafter referred to as "Blood 2006")
- Blood 115:4478-87, 2010 Jun 3 (hereafter referred to as "Blood 2010")
- British Journal of Haematology 161:43-56, 2013 Apr (hereafter referred to as "BJH 2013")
- Cancer Biology & Therapy 8:808-19, 2009 May (hereafter referred to as "CBT 2009")
- Clinical Cancer Research 13:4280-90, 2007 Jul (hereafter referred to as "CCR 2007")
- Leukemia 19:1579-89, 2005 Sep (hereafter referred to as "Leuk 2005")
- Leukemia Research 30:1263-1272, 2006 (hereafter referred to as "LR 2006")
- Molecular Cancer Therapeutics 10:1686-97, 2011 Sep (hereafter referred to as "MCT 2011")
- Molecular Cancer Therapeutics 11:1122-32, 2012 May (hereafter referred to as "MCT 2012")
- Molecular Cancer Therapeutics 13:2886-97, 2014 Dec (hereafter referred to as "MCT 2014")
- Molecular Pharmacology 69:288-98, 2006 Jan (hereafter referred to as "MP 2006")

ORI found that Respondent falsified and/or fabricated data by reporting the results of Western blot experiments and mouse imaging experiments that examined interactions between multiple histone deacetylase and/or proteasome inhibitors in several cancer models. Specifically, Respondent duplicated, reused, and/or relabeled Western blot panels and mouse im-

## Case Summaries of Research Misconduct Findings (cont'd)

ages and claimed they represented different controls and/or experimental results in:

- Blood 2006, Figures 2A and 2B (Tubulin), 2C (c-Jun & Tubulin), and 3E and 3F (Tubulin)
- Blood 2010, Figures 4A and 4C (JNK & Tubulin)
- BJH 2013, Figures 2A and 6B (Tubulin)
- CBT 2009, Figure 4B (Actin)
- CCR 2007, Figures 3B (PARP) and 6A (Tubulin)
- Leuk 2005, Figures 3B (PARP CF) and 4A, 4B, and 4C (Tubulin)
- LR 2006, Figure 3D (Actin – BaF/3-WT)
- MCT 2011, Figures 2B and 3D (Tubulin) and 6B (0 d – CFZ-2.0mg/Kg & 12 d – CFZ + VOR)
- MCT 2012, Figures 3A (JNK & Tubulin, 3B (Tubulin – scram), 3D (Tubulin – pUSE-AKT cl.3), and 6B (CFZ + obato)
- MCT 2014, Figures 3A (JNK 1 & Tubulin), 3B (JNK & Tubulin), and 3C (Tubulin)
- MP 2006, Figures 1D and 1E (Caspase 3, CF Caspase 3, PARP & Tubulin), 2C (PARP), 3B, 4A, and 4B (Tubulin), 6A (Tubulin – U937-pSFFv 12 hr treatment & U937-Bcl-2-ΔN 24 hr treatment), and 9A (Cox-IV)

Dr. Dasmahapatra has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed: (1) to exclude himself for a period of three (3) years from the effective date of the Agreement 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’ 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 (collectively the “Debarment Regulations”); (2) 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 for period of three (3) years, beginning on November 5, 2015; and (3) that the following publications will be retracted or corrected: Blood 2006, Blood 2010, BJH 2013, CBT 2009, CCR 2007, Leuk 2005, LR 2006, MCT 2011, MCT 2012, MCT 2014, and MP 2006.

### **Kaushik Deb, PhD** **University of Missouri-Columbia**

Based upon the evidence and findings of an investigation report by the University of Missouri-Columbia (UM) transmitted to the United States Department of Health and Human Ser-

vices (HHS), Office of Research Integrity (ORI) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Kaushik Deb, former Postdoctoral Fellow, Life Sciences Center, UM, engaged in misconduct in science in research that was supported by National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grants 2 R01 HD021896 and 5 R01 HD042201-05 and National Center for Research Resources (NCRR), NIH, grant 5 R01 RR013438-07.

ORI found that the Respondent intentionally, knowingly, and recklessly fabricated and falsified data reported in the following published paper:

- Deb, K., Sivarguru, M., Yong, H., & Roberts, R.M. “Cdx2 gene expression and trophectoderm lineage specification in mouse embryos.” *Science* 311:992-996, 2006 (hereafter referred to as “Science 311”); this paper was retracted on July 27, 2007

An earlier version of Science 311 had been previously submitted to *Nature* on or about June 24, 2005 (hereafter referred to as “Nature #1”). It was revised and resubmitted to *Nature* on or about August 24, 2005, and ultimately was rejected by *Nature* on September 14, 2005 (hereafter referred to as “Nature #2”).

Specifically, ORI finds by a preponderance of the evidence that the Respondent engaged in misconduct in science by intentionally, knowingly, and recklessly:

1. falsifying and/or fabricating three panels of data in Figure 1 (Figures 1C, 1D, and 1E) in Science 311 and in Nature #1 and Nature #2, by photo-manipulating confocal fluorescent images to falsely represent three-, four-, and six-cell embryos, thereby supporting the paper’s central premise that cells derived from a late-dividing blastomere would be positive for a transcription factor, Cdx2, while the cells derived from a leading blastomere would be Cdx2 negative
2. using photo-manipulation to falsify and fabricate at least 13 panels of confocal image data in Figures 2, 3, and S2, including Figures 2K, 2L, 2Q, 2R, 2V, 2X, 3G, 3H, 3I, S2s, S2t, S2u, and 2W, in Science 311 and in corresponding figures in Nature #1 and Nature #2 so that these images falsely supported the central premise in Science 311 that Cdx2-expressing cells were peripherally located in the embryo
3. falsifying Figures 2G, 3J, 3L, S2V, S2X, S6I, S6J, and S6K in Science 311, Figures 2A, 2C, S4v, and S4x in Nature #1, and Figures 2G, 3I, 3J, and 3K in Nature #2 by re-using and re-labelling the same image to represent different embryos and different experimental conditions
4. falsifying Figure 4 in Science 311 and corresponding figures submitted in Nature #1 and Nature #2 to falsely illustrate that the first dividing cell of a two-cell mouse

## Case Summaries of Research Misconduct Findings (cont'd)

embryo will ultimately differentiate into the trophoblast; specifically, Respondent:

- falsely colored and photomanipulated a single bright-phase image of a three-cell embryo to make it appear as four separate embryos that had been differentially injected with TRD
  - falsely colored and photomanipulated a four-cell embryo to make TRD appear distinctly located in the lagging cell and in its descendent cell, when the actual embryo contained diffuse staining within the sub-zonal, extracellular space
  - photomanipulated a damaged, non-viable two-cell embryo to make it appear viable
  - re-used, falsely colored, and relabeled seven images from an unrelated experiment to falsely represent a time lapse course of eight different images
5. falsifying Figures 5K, 5L, 5N, and 5O in Science 311 by photo-manipulating a single confocal image to falsely represent four different images at two different stages of embryonic development. The images also were presented as Figures 4k, 4l, 4n, and 4o in Nature #1.

The Respondent failed to take responsibility for the fabrication and falsification described in ORI's findings.

The following administrative actions have been implemented for a period of three (3) years, beginning on November 17, 2014: (1) Respondent is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 C.F.R. Part 376 et seq) of Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations"); and (2) Respondent 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.

### **Dr. Igor Dzhura, PhD Vanderbilt University**

Based on an inquiry conducted and admission obtained by Vanderbilt University (VU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Igor Dzhura, former Senior Research Associate, Department of Biomedical Engineering, VU, engaged in research misconduct in research supported by US Public Health Service (PHS) funds, specifically National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL070250, R01 HL062494, P01 HL046681, and K08 HL03727, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NIH, grant R01 AR044864, National Institute of Mental

Health (NIMH), NIH, grant R01 MH063232, National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant U01 AI06223, and National Cancer Institute (NCI), NIH, grant U54 CA113007.

ORI found that Respondent engaged in research misconduct by providing falsified and/or fabricated data to his supervisor and colleagues. Specifically, Respondent:

- submitted falsified cytosolic calcium buffering experiments to his research supervisor by misrepresenting apparent action potential traces; these actually were fluorescent calcium transients merged with sodium calcium exchange currents from a different experiment; Respondent admitted to falsely claiming ten replicates for each trace when only testing three to five cells
- falsified sodium calcium exchange (NCX) activity in Very Long Chain Acid Dehydrogenase Deficient (VLCAD) mice versus wild type mice in a PowerPoint presentation by falsely labeling and manipulating NCX data from a different experiment testing an unrelated compound; the effect was to falsely claim a difference in NCX activity between the two mouse phenotypes
- provided a falsified Figure 6C in a manuscript submitted to Nature Cell Biology, while claiming that the data were based on Respondent's memory of his data that had purportedly been collected and lost; Respondent claimed to have tested one hundred fifty (150) cells for their action potential characteristics when the experimental record only accounted for approximately twenty (20).

ORI found that Respondent engaged in research misconduct by falsifying and/or fabricating the research record of patch-clamp data. Specifically, Respondent:

- created a hierarchy of computer folders containing duplicated and renamed files; the falsified groups of files included eighty-two (82) groups of duplicated files with each group containing two to twenty-one (2-21) duplicates, which made it appear that experiments were conducted when they were not
- used the falsified and/or fabricated data files in Figure 6 of a paper published in the American Journal of Physiology-Heart and Circulatory Physiology (292(5):H2202-H2211, 2007), to represent Ca<sup>+</sup> currents in cardiac myocytes from CLCAD<sup>-/-</sup> mice; specifically, Respondent claimed that Figure 6 represented results from seven (7) mice when the data files were three (3) sets of duplicated and renamed files plus one additional data file. All of the data files were part of larger groups of identical duplicated and renamed data files on the Respondent's hard drive.

ORI found that Respondent engaged in research misconduct by submitting and publishing multiple falsified and/or fabri-

## Case Summaries of Research Misconduct Findings (cont'd)

cated action potential traces and data in at least sixty-nine (69) images in twelve (12) different figures across seven (7) publications and three (3) grant applications by duplication and relabeling of traces; resizing, modifying, and splicing different traces; and modifying and/or duplicating bar graphs.

The evidence established that Respondent engaged in research misconduct, as defined by the PHS regulation, in that he significantly departed from accepted research practices by engaging in the intentional and knowing fabrication and falsification of data files.

Dr. Dzhura has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on October 29, 2014: (1) to exclude himself 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' 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 (collectively the "Debarment Regulations"); (2) 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 (3) to retract or correct the following publications:

- Nature Cell Biology 2:173-177, 2000
- J. Physiol. 535.3:679-687, 2001
- Circulation 106:1288-1293, 2002
- J. Physiol. 545.2:399-406, 2002
- J. Physiol. 550.3:731-738, 2003
- FASEB J. 19:1573-1585, 2005
- Molecular Cell 23:641-650, 2006

### **Ryousuke Fujita, PhD** **Columbia University**

Based on the report of an investigation conducted by Columbia University (CU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Ryousuke Fujita, former Postdoctoral Scientist, Taub Institute for the Aging Brain, Departments of Pathology and Cell Biology and Neurology, CU Medical Center, engaged in research misconduct in research supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant R01 NS064433 and National Institute of Aging (NIA), NIH, grant R01 AG042317.

ORI found that Respondent engaged in research misconduct by falsifying and fabricating data for specific protein expres-

sions in human-induced neuronal (hiN) cells derived skin fibroblasts of Alzheimer's disease patients and unaffected individuals in seventy-four (74) panels included in figures in the following two (2) publications and one (1) unpublished manuscript:

- Cell 146:359-371, 2011 (hereafter referred to as "Cell 2011").
- Nature 500:45-53, 2013 (hereafter referred to as "Nature 2013").
- "Human induced neuron models of APOE4-associated Alzheimer's disease display altered APP endocytosis and processing." Unpublished manuscript.

ORI found that Respondent engaged in research misconduct by knowingly and intentionally fabricating and falsifying research in seventy-four (74) panels included in figures in Cell 2011, Nature 2013, and the unpublished manuscript. Respondent inflated sample numbers and data, fabricated numbers for data sets, manipulated enzyme-linked immunosorbent assay (ELISA) analysis, mislabelled immunofluorescent confocal images, and manipulated and reused Western blot images.

Specifically, the Respondent:

- fabricated numbers for the data presented as a bar graph in nine (9) panels in Figures S6E, S6H, and S6J in Cell 2011, Figures 3B and S12 in Nature 2013, and Figures 2F, 4B, 4D, and 4F in the unpublished manuscript
- falsely inflated the sample size of quantitative data presented as bar graphs in fifty-three (53) panels in Figures 6B, 7I, and S6J in Cell 2011, Figures 3G, 3H, 4C, S10, S11b-h, S12d-f, S13a, S13c, S14b-c, S15b-i, and S16a-f in Nature 2013, and Figures 4b, 4d, 4f, 4i, 6c-d, S1n, S1o, S2a-b, and S4c-k in the unpublished manuscript
- falsely manipulated ELISA analysis to achieve desired results presented as bar graphs in nine (9) figure-panels in Figure 6B in Cell 2011 and Figures 2D, 2E, 3G, 3H, and S10a-d in Nature 2013
- falsely inflated the numerical values of the data in Figure 7I in Cell 2011 by a factor of 10 to improve results and appear consistent with data presented in supplementary information published with the paper
- falsely reversed the labeling of immunofluorescent confocal images in Figures 7M and 7N in Cell 2011 and Figure S13A in Nature 2013 to obtain the desired results
- flipped and resized the Western blot image for APP panel from Figure 12b and falsely reused it to represent APP results under completely different experimental conditions in Figure 12c in Nature 2013



 Case Summaries of Research Misconduct Findings (cont'd)

Dr. Fujita has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on March 18, 2015: (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government referred to as “covered transactions” pursuant to HHS’ 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 (collectively the “Debarment Regulations”); and (2) to exclude himself voluntarily from serving in any advisory capacity to the US Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

**Maria C.P. Geraedts, PhD**  
**University of Maryland, Baltimore**

Based on the report of an investigation conducted by the University of Maryland, Baltimore (UMB) and analysis conducted by ORI in its oversight review, ORI and UMB found that Dr. Maria C.P. Geraedts, former postdoctoral fellow, Department of Anatomy and Neurobiology, UMB, engaged in research misconduct in research supported by National Institute on Deafness and Other Communication Disorders (NIDCD), National Institutes of Health (NIH), grant R01 DC010110.

ORI found falsified and/or fabricated data included in the following two (2) publications:

- Am J Physiol Endocrinol Metab 303:E464-E474, 2012 (hereafter referred to as “AJP 2012”)
- Journal of Neuroscience 33(17):7559-7564, 2013 (hereafter referred to as “JN 2013”)

As a result of the UMB investigation, JN 2013 and AJP 2012 have been retracted.

ORI found that Respondent falsified and/or fabricated bar graphs in AJP 2012, by changing ELISA-based measurements to produce the desired result for secretion of glucagon-like peptide-1 (GLP-1) from intestinal explants from various mouse strains in:

- Figure 2 for GLP-1 release from duodenum (2A & D), jejunum (2B & E), and ileum (2C & F)
- Figure 3 for GLP-1 release from colon (3A & C) and rectum (3D)
- Figure 4 for GLP-1 release from ileum (4A) and colon (4C) in the presence or absence of an ATP-sensitive K<sup>+</sup> channel inhibitor

ORI found that Respondent falsified and/or fabricated bar graphs in Figure 1, JN 2013 by changing ELISA-based mea-

surements to produce the desired result for the secretion of peptides found in taste buds (GLP-1, glucagon, or neuropeptide Y) from mouse lingual epithelium exposed to various concentrations of stimuli (glucose, sucralose, MSG, polycose). These bar graphs also were included as Figure 7 in grant application R01 DC010110-06.

Both the Respondent and the US Department of Health and Human Services (HHS) want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement (Agreement) to resolve this matter. Respondent stated that she is not currently involved in US Public Health Service (PHS)-supported research and has no intention of applying for or engaging in PHS-supported research or otherwise working with PHS. Respondent neither admits nor denies ORI’s findings of research misconduct; the settlement is not an admission of liability on the part of the Respondent.

Dr. Geraedts has entered into a Voluntary Settlement Agreement with ORI and UMB, in which she voluntarily agreed to the administrative actions set forth below. The administrative actions are required for three (3) years beginning on the date of Dr. Geraedts employment in a position in which she receives or applies for PHS support on or after the effective date of the Agreement (September 22, 2015). If the Respondent has not obtained employment in a research position in which she receives or applies for PHS support within one (1) year of the effective date of the Agreement, the administrative actions set forth below will no longer apply. Dr. Geraedts has voluntarily agreed: (1) to have her research supervised as described below and notify her employer(s)/ institution(s) of the terms of this supervision; Respondent agreed that prior to the submission of an application for PHS support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she will not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan; (2) that any institution employing her 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 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 for period of three (3) years beginning on September 22, 2015.

## Case Summaries of Research Misconduct Findings (cont'd)

### Bin Kang, PhD

#### Oklahoma Medical Research Foundation

Based on the Respondent's admission, an assessment conducted by the Oklahoma Medical Research Foundation (OMRF), and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Bin Kang, Postdoctoral Fellow, Immunobiology and Cancer Research Program, OMRF, engaged in research misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants AI056129 and AI104057.

ORI and OMRF found that Respondent engaged in research misconduct by reporting falsified data in:

- "Asb2 regulates the activity of SCF E3 ubiquitin ligases by antagonizing CAND1-mediated exchange of F-box proteins," submitted to *Molecular Cell* on June 26, 2014; hereafter referred to as the "original *Molecular Cell* manuscript"
- the revised version of "Asb2 regulates the activity of SCF E3 ubiquitin ligases by antagonizing CAND1-mediated exchange of F-box proteins," submitted to *Molecular Cell* on September 29, 2014; hereafter referred to as the "revised *Molecular Cell* manuscript"
- grant application CA189216-01 submitted to the National Cancer Institute (NCI), NIH; hereafter referred to as the "original NCI grant application"
- grant application CA189216-01A1 submitted to NCI, NIH; hereafter referred to as the "revised NCI grant application"

ORI found that Respondent knowingly falsified and/or fabricated Western blot gel images by duplication, reuse and re-labeling, and/or alteration through contrast, rotation, and/or scale of the images.

Specifically, Respondent included falsified images in all of the figures (Figures 1-6 and S1-5) in the original *Molecular Cell* manuscript, all of the figures (Figures 1-6 and S1-7) in the revised *Molecular Cell* manuscript, Figures 2-4, 9, and 11 in the original NCI grant application, and Figures 3-5, 10, and 11 in the revised NCI grant application.

Dr. Kang has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on December 23, 2014: (1) to have his research supervised; Respondent agreed to ensure that prior to the submission of an application for US 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, the institution employing him must submit a plan for supervision of his duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity

of Respondent's research contribution; Respondent agreed that he will not participate in any PHS-supported research until a plan for supervision 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 must 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.

### Peter Littlefield

#### University of California, San Francisco

Based on an assessment conducted by the University of California, San Francisco (UCSF), the Respondent's admission, and analysis conducted by ORI, ORI and UCSF found that Mr. Peter Littlefield, Graduate Student on a leave of absence from the Tetrad Graduate Program, UCSF, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), training grant T32 GM007810 and grant R01 GM109176.

ORI found that the Respondent engaged in research misconduct by falsifying and/or fabricating data in the following two (2) publications:

- *Science Signaling* 7:ra114, 2014 (hereafter referred to as "Paper 1")
- *Chemistry & Biology* 21:453-458, 2014 (hereafter referred to as "Paper 2")

ORI found that Respondent knowingly falsified and/or fabricated data and related text by altering the experimental data to support the experimental hypothesis. Specifically:

1. ORI found falsified and/or fabricated data in Paper 1 in:
  - a. Figure 5B by manipulation of the HER3 protein concentrations in the experiment to provide the desired outcome
  - b. Figure 6C for the identification of the kinase domain construct EGFR-V924R by falsely claiming that both EGFR and HER3 contained the kinase domains and the full JM segments, when the JM-HER3 construct included cloning tags
  - c. Figure 6D by manually manipulating the error bars to increase statistical significance of the kinase assay

## Case Summaries of Research Misconduct Findings (cont'd)

2. ORI found falsified and/or fabricated data in Paper 2 in:
  - a. Figure 3C by manually altering some of the data points by 10-20% support the desired hypothesis
  - b. Figure 4A by manipulating data points and reducing error bars and failing to report that JM-HER3 construct had cloning tags
  - c. Figure 4B by reducing several data points by ~ 15%

Mr. Littlefield has entered into a Voluntary Settlement Agreement and has voluntarily agreed: (1) to have his research supervised for period of three (3) years beginning on August 4, 2015; Respondent agreed that prior to the submission of an application for US Public Health Service (PHS) support for a research project on which his participation is proposed and prior to his participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of his research contribution; Respondent agreed that he will not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan; (2) that for period of three (3) years beginning on August 4, 2015, 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; (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 for period of three (3) years beginning on August 4, 2015; and (4) to retraction or correction of the following papers:

- Science Signaling 7:ra114, 2014
- Chemistry & Biology 21:453-458, 2014

**Julie Massè**  
**Pennsylvania State University (PSU)**

Based on an assessment conducted by the Pennsylvania State University College of Medicine (PSU-COM) and the Respondent's admission, ORI and PSU found that Ms. Julie Massè, former postdoctoral scholar, PSU-COM, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant 4 R00 CA138498.

ORI found that the Respondent knowingly engaged in research misconduct by falsifying and/or fabricating Western

blot data and analyses that were including in the following manuscript:

- "Cellular invasion following p120-catenin loss is mediated by AP-1, ITGA2 and MMP11," submitted to Molecular Cancer Research (hereafter referred to as the "Molecular Cancer Research manuscript")

ORI found that the Respondent knowingly falsified and/or fabricated Western blot images, by manipulating the images to give the desired results, and quantitative PCR data and cell invasion and migration data, which were included in Figures 2, 3, S1, and S2 in the Molecular Cancer Research manuscript.

Specifically, ORI found that the Respondent included falsified and/or fabricated data and images in the following figures, and the corresponding text, in the Molecular Cancer Research manuscript:

1. Bands were cut and pasted from different Western blots for the following figures:
  - a. Figures 2A, lanes 2 and 3, for P-cJun (S73)
  - b. Figure 2D, lanes 4 and 6, bands identified as ITGA2
  - c. Figure 3B, bands identified as ITGA2 and MMP11
  - d. Figure 3D, bands identified as ITGA2 and MMP11 for lanes M2Neo- $\uparrow$ ITGA2 control and  $\downarrow$ MMP1
  - e. Figure 3E, bands identified as ITGA2 and MMP11 for lanes M2KO- $\downarrow$ ITGA2 control and M2KO- $\downarrow$ ITGA2- $\uparrow$ MMP11
  - f. Figure S1A, bands identified as P-cJun (S73)
  - g. Figure S2A, bands identified as P-cJun (S73)
  - h. Figure S2C, bands identified as P-cJun (S73)
  - i. Figure S2E, bands identified ITGA2 and MMP11
  - j. Figures S4B and C, identical bands were used for  $\beta$ -actin
2. Numbers were increased or decreased in cell invasion and migration assays to give the desired results in the following figures:
  - a. Figure 2B, for M2KO-DMSO cells and M2KO-SR11302 cells
  - b. Figure 3F, for M2Neo- $\uparrow$ ITGA2  $\downarrow$ MMP11
  - c. Figure 3G, for M2KO- $\downarrow$ ITGA2  $\uparrow$ MMP11
  - d. Figure S1B, for F2KO-cJun peptide
  - e. Figure S2B, for F2KO-cJun DMSO and F2KO-cJun SR11302
  - f. Figure S2D, for F2KO-cJun peptide
  - g. Figure S2F, for F2Tom- $\uparrow$ ITGA2 and F2KO- $\downarrow$ ITGA2 peptide
  - h. Figures S4A, B, C, and D, for the migration for M2KO and F2KO cells
3. qPCR numbers were altered in Figure 2C, for M2KO-DMSO-PcJun ChIP and for M2KO-SR11302-PcJun ChIP, to give the desired result of PcJun binding to ITGA2 promoter.

## Case Summaries of Research Misconduct Findings (cont'd)

Ms. Massè has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of two (2) years, beginning on July 6, 2015: (1) to have her research supervised; Respondent agreed that prior to the submission of an application for US Public Health Service (PHS) support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she will not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan; (2) that any institution employing her 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 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.

### **Anil Potti, M.D.**

#### **Duke University School of Medicine**

Based on the reports of investigations conducted by Duke University School of Medicine (Duke) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Anil Potti, former Associate Professor of Medicine, Duke, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant R01 HL072208 and National Cancer Institute (NCI), NIH, grants R01 CA136530, R01 CA131049, K12 CA100639, R01 CA106520, and U54 CA112952.

ORI found that Respondent engaged in research misconduct by including false research data in the following published papers, submitted manuscript, grant application, and the research record as specified in 1-3 below. Specifically, ORI found that:

1. Respondent stated in grant application 1 R01 CA136530-01A1 that 6 out of 33 patients responded positively to dasatinib when only 4 patients were enrolled and none responded and that the 4 CT scans presented in Figure 14 were from the lung cancer study when they were not.
2. Respondent altered data sets to improve the accuracy of predictors for response to treatments in a submitted paper and in the research record by:

- reversing the responder status of 24 out of 133 subjects for the adriamycin predictor in a manuscript submitted to Clinical Cancer Research
  - switching the cancer recurrence phenotype for 46 out of 89 samples to validate the LMS predictor in a file provided to a colleague in 2008
  - changing IC-50 and R-code values for the cisplatin predictor in a data set provided to NCI in 2010
3. Respondent reported predictors and/or their validation by disregarding accepted scientific methodology so that false data were reported in the following:
    - Blood 107:1391-1396, 2006: describing a predictor for thrombotic phenotypes
    - New England Journal of Medicine 355:570-580, 2006: describing a predictor of lung cancer relapse
    - Nature Medicine 12:1294-1300, 2006: describing a predictor for the response to the chemotherapeutic drugs topotecan and docetaxol
    - Journal of Clinical Oncology 25:4350-4357, 2007: describing a predictor for the response to the chemotherapeutic drug cisplatin
    - Lancet Oncology 8:1071-1078, 2007: describing a predictor for the response to the combination of the chemotherapeutic drugs fluorouracil, epirubicin, and cyclophosphamide or docetaxol, epirubicin, and docetaxol
    - Journal of the American Medical Association 299:1574-1587, 2008: describing a predictor for breast cancer relapse
    - Public Library Science One 3:31908, 2008: describing a predictor for the response to the chemotherapeutic drugs paclitaxel, 5-fluorouracil, adriamycin, and cyclophosphamide
    - Proceedings of the National Academy of Sciences 105:19432-19437, 2008: describing a predictor of colon cancer recurrence
    - Clinical Cancer Research 15:7553-7561, 2009: describing a predictor for the response to the chemotherapeutic drug cisplatin

As a result of Duke's investigation, the published papers listed above were retracted.

Respondent has entered into a Voluntary Settlement Agreement with ORI. Respondent neither admits nor denies ORI's findings of research misconduct; the settlement is not an admission of liability on the part of the Respondent. The parties entered into the Agreement to conclude this matter without further expenditure of time, finances, or other resources. Respondent has not applied for or engaged in US Public Health

## Case Summaries of Research Misconduct Findings (cont'd)

Service (PHS)-supported research since 2010. Respondent stated that he has no intention of applying for or engaging in PHS-supported research or otherwise working with PHS. However, the Respondent voluntarily agreed: (1) that if the respondent obtains employment in a research position in which he receives or applies for PHS support within five years of the effective date of the Agreement (September 23, 2015), he shall have his research supervised for a period of five years; (2) 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 contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed 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 for period of five years beginning on September 23, 2015.

### **Venkata J. Reddy** **University of Minnesota**

Based upon the evidence and findings of an investigation report by the University of Minnesota (UMN), an investigation conducted by another Federal agency, and additional information obtained by the Office of Research Integrity (ORI) during its oversight review of the UMN investigation, ORI found that Mr. Venkata J. Reddy, former Graduate Student, Department of Chemistry, UMN, engaged in research misconduct in research that was included in grant application R01 GM095559-01A1, submitted to the National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

ORI found by a preponderance of the evidence that the Respondent intentionally and knowingly engaged in research misconduct by falsifying and/or fabricating data that was provided to his mentor to include in grant application R01 GM095559-01A1 submitted to NIGMS, NIH, to obtain US Public Health Service (PHS) funds. Specifically, ORI found that the Respondent falsified data included in Figures 4, 9, 11, 15, and 25 in R01 GM095559-01A1 for enantiomeric excess ("ee") to falsely show a high degree of selectivity for

one enantiomer over another by a cut-and-paste method and manipulation of the instrument to give the desired result. Respondent also falsified the underlying nuclear magnetic resonance spectroscopy (NMR) data for Compound 22 reported in Figure 15 in R01 GM095559-01A1 by a cut-and-paste method to manipulate the NMR spectra and give the desired result.

Dr. Reddy has been debarred by the Federal agency with joint jurisdiction for a period of five (5) years, ending on August 26, 2018. ORI has implemented the following administrative action to coincide with the government-wide debarment: (1) Respondent 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.

### **James P. Warne, PhD** **University of California** **San Francisco**

Based on an assessment conducted by the University of California San Francisco (UCSF), the Respondent's admission, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. James P. Warne, former Senior Scientist, Diabetes Center, UCSF School of Medicine, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants DK080427, DK007161, and DK063720.

ORI found that Respondent engaged in research misconduct by falsifying data that were included in the following two (2) publications and two (2) grant applications:

- Cell Metabolism 14:791-803, 2011 (hereafter referred to as the "Cell Metabolism paper")
- Journal of Neuroscience 33(29):11972-85, 2014 (hereafter referred to as the "Journal of Neuroscience paper")
- R01 DK080427-06A1 submitted to NIDDK, NIH
- R01 AA022665-01A1 submitted to the National Institute on Alcohol Abuse and Alcoholism (NIAAA), NIH

ORI found that Respondent falsified data and related text by altering the experimental data to support the experimental hypothesis. Specifically:

1. Respondent fabricated graphs purported to represent the results of ten (10) different ELISA experiments measuring norepinephrin (NE) or leptin levels in wild-type mice, in AGRP knockout mice, or in AGRP RNAi mice and controls that had received brain infusions of alpha-MPT, a tyrosine hydroxylase inhibitor or vehicle and leptin or AGRP in the following figures:

## Case Summaries of Research Misconduct Findings (cont'd)

- Figures 2D/E, 3G, and 7C in the Cell Metabolism paper
- Figures 6B/C/E, Figure 8C, and Figure 9H in the Journal of Neuroscience paper; Figures 6B/C/E of the Journal of Neuroscience paper also were included as Figures 5A/C/B in grant application DK080427-06A1, and Figure 8C of the Journal of Neuroscience paper also was included as Figure 8C in grant application DK080427-06A1
- Figure 10B in grant application DK080427-06A1

2. Respondent fabricated graphs purported to represent the results of six (6) different quantitative polymerase chain reaction (Q-PCR) experiments measuring mRNA levels in mouse liver from wild-type or AGRP RNAi mice and controls that had received brain infusions of alpha-MPT, a tyrosine hydroxylase inhibitor or vehicle and leptin, AGRP knockout mice injected with ethanol, or wild-type mice injected with ethanol and caffeine in the following figures:

- Figure 2F in the Cell Metabolism paper
- Figures 5A, 6F, and 9A in the Journal of Neuroscience paper; Figure 5A of the Journal of Neuroscience paper also was included as Figure 4A in grant application DK080427-06A1, and Figure 6F of the Journal of Neuroscience paper also was included as Figure 7A in grant application DK080427-06A1
- Figure 3B in grant application AA022665-06A1

Dr. Warne has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed: (1) to have his research supervised for a period of three (3) years, beginning on November 18, 2014; 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 his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; 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 for a period of three (3) years, beginning on November 18, 2014, 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; (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 for a period of three (3) years, beginning on November 18, 2014; and (4) that as a condition of the Agreement, the senior authors will request retraction or correction of the following papers:

- Cell Metabolism 14:791-803, 2011
- Journal of Neuroscience 33(29):11972-85, 2013

### Dong Xiao, PhD University of Pittsburgh

Based on the report of an inquiry conducted by the University of Pittsburgh (UP), additional analysis conducted by ORI in its oversight review, and an admission by the Respondent that he had "intentionally fabricated data contained in a paper entitled 'Guggulsterone inhibits prostate cancer growth via inactivation of Akt regulated by ATP citrate signaling,' specifically Figure 6G," ORI found that Dr. Dong Xiao, former Research Assistant Professor, Department of Urology, UP, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant R01 CA157477.

ORI found that Respondent engaged in research misconduct by reporting falsified data in Figures 1, 4, 5, S2, and S3 in the following paper published online:

- Gao, Y., Zeng, Y., Tian, J., Kslam, M.S., Jiang, G., & Xiao, D., "Guggulsterone inhibits prostate cancer growth via inactivation of Akt regulated by ATP citrate signaling." *Oncotarget*, June 26, 2014 [Epub ahead of print], PMID: 24980815; hereafter referred to as the "Oncotarget paper."

Specifically, in the Oncotarget paper, Respondent:

- falsely stated that 10 mice per group were used to obtain data for tumor volume (Figure 1A) and tumor weight (Figure 1B) when data for only four mice per group were available
- falsified the results for C-caspase 3 and phosphorylated Akt in the Western blots presented in Figure 1D to claim that treatment of tumor bearing mice with Z-Gug significantly enhanced C-caspase 3 activity and significantly inhibited Akt phosphorylation, while the original data showed no significant effect for either activity
- falsified Figure 4C by manipulating p-Akt bands to show that Z-Gug alone and in combination with PHTM significantly inhibited Akt phosphorylation in PC3 and LNCaP human prostate cancer cell lines; the numbers above each band representing the fold change human prostate cancer cell lines; the numbers above each band representing the fold change in expression relative to the DMSO control also were falsified for p-ACLY (LNCaP cell line) and p-Akt (PC3

## Case Summaries of Research Misconduct Findings (cont'd)

and LNCaP cell lines) compared to the values provided to the Respondent

- falsified Figure 4D by substituting bands for p-ACLY for those provided to him to allow Respondent to claim that Z-Gug significantly inhibited phosphorylation of ACLY in lysates of prostate tumors obtained from mice, when the original data showed no effect
- falsified Figures 5C and 5D to show that treatment of PC3 and LNCaP cells with Z-Gug alone and with Z-Gug plus si-RNA targets to ACLY stimulated Caspase 3/7 activity, when the original data provided to him showed no significant effect of either treatment in PC3 cells and no effect of Z-Gug alone in LNCaP cells
- falsified Figures 6G and 6H; these figures purported to show that N-acetyl-L-cysteine (NAC), an inhibitor of reactive oxygen species (ROS), reversed the inhibition of Akt phosphorylation caused by Z-Gug in PC3 cells (Figure 6G) and LNCaP cells (Figure 6G) when no Akt data for this protocol was available to the Respondent; Respondent admitted to falsifying Figure 6G
- falsified Figures S2B and S3B by altering data provided to him; these experiments are complementary to those shown in Figures 5C and 5D, except that the effect of Z-Gug and Z-gug plus si-RNA on Caspase 3/7 activity utilized on si-RNA was directed to Akt activity. The original data showed no significant effect of either treatment in PC3 cells and no effect of Z-Gug on LNCaP cells, while both treatments were claimed to be significant inducers of caspase activity in both cell lines in the published figures.

Dr. Xiao has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of three (3) years, beginning on December 23, 2014: (1) to have his research supervised; Respondent agreed to ensure that prior to the submission of an application for US 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, the institution employing him must submit a plan for supervision of his duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he will not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon plan for supervision; (2) that any institution employing him must 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.

### H. Rosie Xing, PhD University of Chicago

Based on the report of an investigation conducted by the University of Chicago (UC) and additional analysis by ORI in its oversight review, ORI found that Dr. H. Rosie Xing, former Assistant Professor, UC, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant R01 CA098022.

ORI found that Respondent engaged in research misconduct (42 C.F.R. § 93.103-104) by using images that had been among a set of manipulated images produced while at another institution, which had been found to be false by that institution. ORI found that Respondent falsely reported these images in Figures 1D, 2A, and Supplementary Figures 1B and 1C in *Molecular Cancer Therapeutics* 9:2724-36, 2010. The Respondent does not agree with ORI's finding of research misconduct and asserts that there are extenuating circumstances for her actions.

Specifically, ORI found that Respondent:

1. included falsely labeled immunoblots in Figures 1D and 2A as follows:
  - a. Figure 1D (lower panel), representing the total ERK levels in extracts from cells exposed to 15 Gy of gamma radiation for 0-120 minutes, by using results from an unrelated experiment for MAPK levels in extracts from cells exposed to 2, 12, or 20 Gy of gamma irradiation for 1, 5, 20, or 60 minutes
  - b. Figure 2A (KSR1 panel), representing a control Flag-KSR1 immunoblot for extracts of cells transfected with control (TRE), wild-type KSR (KSR-S), or dominant negative inactive KSR (DN-KSR) exposed to no radiation or 5 minutes gamma irradiation, by using results from an unrelated experiment for KSR-transfected cells (KSR-S) irradiated with 0, 2, 5, 20, 15, 20 Gy irradiation
  - c. Figure 2A (ERK panel), representing a control ERK immunoblot for extracts of cells transfected with control (TRE), wild-type KSR (KSR-S), or dominant negative inactive KSR (DN-KSR) exposed to no radiation or 5 minutes gamma irradiation, by using results from an unrelated experiment for KSR-transfected cells (KSR-S) irradiated with 0, 2, 5, 10, 15, 20 Gy irradiation

## Case Summaries of Research Misconduct Findings (cont'd)

2. included falsified images in Figures 1D, 2A, and Supplementary Figures 1B and 1C by duplicating bands within the figures as follows:
  - a. Figure 1D (top panel) for an immunoblot for p-ERK in A431 cells, by using the same bands to represent cells treated with ionizing radiation for 5 and 10 minutes with the bands for 60 and 90 minutes
  - b. Figure 2A (top) for an in vitro kinase assay for p-GST-Elk-1, by duplicating lanes 2 and 5 to represent the control plasmid (TRE) at 5 minutes post radiation (lane 2) and the dominant negative inactive KSR (DN-KSR) NT lane (lane 5)
  - c. Supplementary Figure 1B (middle panel) for an in vitro kinase assay for p-GST-MEK, by using the same bands to represent cells exposed to 5 and 20 Gy ionizing radiation
  - d. Supplementary Figure 1C (top panel) for an immunoblot for p-MEK1/2, by using the same bands to represent cells exposed to 2 and 20 Gy ionizing radiation

Dr. Xing has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed: (1) that if within three (3) years from the effective date of the Agreement, Respondent receives or applies for US Public Health Service (PHS) support, Respondent agrees to have her PHS-supported research supervised for a period of three (3) years beginning on the date of her employment in which she receives or applies for PHS support, and to notify her employer(s)/institution(s) of the terms of this supervision; 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 her 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 she 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 if within three (3) years from the effective date of this Agreement, Respondent receives or applies for PHS support, for a period of three (3) years beginning on the date of her employment in which she receives or applies for PHS support, any institution employing her to work on PHS-supported projects 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 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 for a period of three (3) years beginning on November 13, 2014.

### Disclaimer

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