THE OFFICE OF RESEARCH INTEGRITY®

NEWSLETTER

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IN THIS ISSUE:

MESSAGE from the DIRECTOR

The last several months have kept ORI quite busy interacting on numerous fronts with the community we serve. Along with our co-sponsors, we have hosted our regular RIO Bootcamps, our Quest for Research Excellence conference, and introduced a few new events in the spirit of strengthening the research integrity community's multi-faceted mission among a wide range of stakeholders.

In April, we hosted a new train-the-trainer short course on Responsible Conduct of Research (RCR) instruction. The breadth of experience and knowledge shared by our extensive panel of instructors provided our attendees with a wealth of ideas to take back to their home institutions. Another goal of the course was to plant the seeds for a growing network of RCR instructors, similar to the RIO network that grew out of the RIO Bootcamps. Because of the positive feedback on the RCR course, we have already scheduled a second offering with our co-sponsor, the University of California—San Diego, for September 12-13. We look forward to making the RCR instruction course a regular event in the ORI repertoire.

Over the summer, we spoke on two occasions about the relationship between research integrity and data management to audiences of research administrators. Alongside our federal partners at NIH and NSF OIG, we explored the linkage between federal grant requirements for maintaining data and the challenges of investigating research misconduct allegations when the respondent claims that the data are lost or missing. We encouraged administrators to think beyond technical compliance with grant conditions and to aim for responsible stewardship of data. Many of the research administrators seemed eager to go home to their institutions and begin a dialogue with their RIOs. We hope that these interactions are taking place, increasing in frequency, and broadening out to other parts of the research infrastructure to break down any silos that might exist.

Breaking down the silos has certainly been a focus for us, so much so that it was the theme of Quest for Research Excellence 2017, which we co-hosted with PRIM&R and the George Washington University. On paper, the conference presented four different "tracks," focused on RIOs, attorneys, publishers, and RCR educators. In reality, each session of the program introduced attendees who identified with at least one of these tracks to the perspectives of the other tracks. There were some lively discussions across disciplines.

Immediately after Quest, we conducted a small pilot course on evidence sequestration for RIOs who had previously completed a RIO Bootcamp. Securing, acquiring, and preserving

MESSAGE from the DIRECTOR

evidence in a sound manner are essential to good investigations. No two sequestrations are identical. We wanted a course to demonstrate options and designed it with interactive elements using role players in a live exercise. Because of the importance of digital evidence, we also had a detailed discussion on the challenges of digital preservation in the current research environment with some practical approaches for talking with the IT professionals involved. Our colleagues from HHS OIG and NSF OIG shared some of their techniques for documenting the evidence collection process and dealing with difficult situations in the administrative setting. We received some great feedback, which we plan to incorporate into the next iteration of the course in the coming year. One thing we learned was that a single day was too short to cover the full range of topics that contribute to a good sequestration. We are excited to develop this pilot further and maybe incorporate some additional advanced topics into a multi-day exercise.

Stay tuned.

Kathryn Partin, Ph.D.
Director

FALSIFICATION AND FORGERY

Administrative Law Judge Upholds ORI's Findings of Research Misconduct against Former Biochemistry Professor

On May 22, 2017, Administrative Law Judge (ALJ) Leslie Rogall granted summary judgment to ORI, upholding ORI's findings of research misconduct and HHS's proposed administrative actions against Respondent Frank Sauer, Ph.D., a former associate professor of biochemistry at the University of California, Riverside (UCR). On June 22, 2017, after the 30-day period required by the HHS regulation, the ALJ's recommended decision to the Acting Assistant Secretary for Health became the final agency decision. See 82 Fed. Reg. 31334 (July 6, 2017).

In June 2016, ORI sent a charge letter to Dr. Sauer, notifying him of ORI's findings of research misconduct and proposed HHS administrative actions. ORI found that Dr. Sauer committed research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating images in seven National Institutes of Health (NIH) grant applications and three published papers by manipulating, reusing, and falsely labeling images of autoradiograms and gels to represent falsely the results of different experiments on the epigenetic regulation of gene expression. Prior to ORI's findings, another federal agency, the National Science Foundation (NSF), had imposed a five-year government-wide debarment on Dr. Sauer for similar misconduct. ORI therefore proposed as administrative actions a prohibition on serving in an advisory capacity to the Public Health Service through July 27, 2020, the end date of his debarment, and that ORI send a notice to a scientific journal that published one of Dr. Sauer's papers (PLoS One 5(5):e10581, 2010) that retraction or correction of the paper is warranted (the other papers at issue had already been retracted).

Pursuant to 42 C.F.R. § 93.501, Dr. Sauer filed a request for an administrative hearing before an ALJ of the Departmental Appeals Board (DAB) to dispute ORI's findings and the proposed administrative actions. Both parties filed cross motions for summary judgment. In his summary judgment brief, Dr. Sauer admitted that the images in his publications and grant applications were knowingly and intentionally falsified, but denied culpability, claiming that a member of an anti-gene technology activist group had falsified Dr. Sauer's data in order to subvert gene-technology research. As evidence for his claim, Dr. Sauer submitted an uncorroborated declaration purportedly by an individual named "Rune Dreser," who allegedly stated that he had hacked into Dr. Sauer's computers and altered Dr. Sauer's research results. The declaration, written in German and purportedly notarized by a notary in Germany, did not contain the notary's name, and the signature of the notary was illegible. Noticing this irregularity, the HHS attorney for ORI emailed the notarial office in Germany to inquire about the authenticity of the notarization. The director of the notarial office responded that the notary seal and signature were most likely forgeries.

The ALJ granted summary judgment to ORI because the undisputed material facts established that Dr. Sauer intentionally, knowingly, or recklessly reported falsified and/or fabricated images in his grant applications and publications, and in doing so, Dr. Sauer significantly departed from accepted practices of the relevant research community. The ALJ did not reach the issue of whether "Rune Dreser" had falsified the underlying images, since the ALJ held that Dr. Sauer was liable for reporting the false images regardless of who initially created them. The ALJ also held that the proposed administrative actions were reasonable.

RESEARCH INTEGRITY NEWS

Checklist Allows Institutions to Evaluate Their Policies and Procedures

Institutions that receive or apply for research, research-training, or research-related grant or cooperative agreements from the Public Health Services (PHS) must have written policies and procedures for responding to allegations of research misconduct that comply with the PHS regulation (42 CFR Part 93). As part of its Assurance Program, ORI works with institutions by performing policy reviews and making recommendations to ensure that their policies and procedures are in compliance with the regulation. To facilitate the policy review process, ORI released a checklist that allows institutions to self-assess their policies. The checklist is similar to what ORI uses internally for policy reviews.

Download the Policy Review Checklist (pdf)

"In more than two decades of conducting policy reviews, we frequently encountered institutional policies that were deficient in one or more areas," said John Butler, Compliance Officer, who began working at ORI during its inception. "The new checklist is an excellent tool for institutions that are rewriting their policies or just want to make sure they're in compliance."

The checklist has two parts. The first includes the elements that are required to be in the written policies and procedures as stated in 42 CFR Part 93.304. Typically, if ORI finds any of these elements missing from institutional policies, ORI notifies the institutions about the deficiencies and works with them to make their policies compliant with the regulation. The second part of the checklist includes the elements that ORI highly recommends that institutions to include in their policies and procedures. Although the regulation does not require these elements to be included in the written institutional policy, these elements are important for institutions to properly handle allegations of research misconduct.

"The policies and procedures serve as instructions for institutions to follow when they're faced with research misconduct allegations," said Butler. "Having detailed procedures in place helps prevent improper actions that may negatively affect an investigation. The procedures also provide whistleblowers and respondents with the information they need to know about the institutions' misconduct proceedings." Butler continued, "In fact, institutions are required by the regulation [§93.308] to provide a copy of the policies and procedures to respondents if an inquiry determines that an investigation is warranted."

To remain in compliance with regulation, institutions must share their policies and procedures not only with respondents, but also with all institutional members who participate in PHS-funded research, research training, or apply for PHS research support (§93.302). Informing the entire research staff about how to report research misconduct and how the institution handles allegations is an important part of fostering a culture of research integrity.

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INTERVIEW WITH CO-FOUNDER, LAURAN QUALKENBUSH

New Association Provides Resources for RIOs

Research administrators have several professional associations that they can turn to for resources and training. Additionally, research administrators commonly have several colleagues within the institution with whom they can collaborate. For handling allegations of research misconduct, institutions often have only one person who is responsible, the Research Integrity Officer (RIO). Consequently, finding assistance and support (specifically for handling research misconduct) within an institution can be challenging for RIOs.

Lauran Qualkenbush

"RIOs often work in isolation on highly confidential and extremely complex matters..."

To help address this issue, the Association of Research Integrity Officers (ARIO) was formed unofficially in 2013 and formally incorporated as an association in 2016. ARIO was formed by five colleagues: Anne Ackenhusen, Sheila Garrity, Debra Schaller-Demers, Lauran Qualkenbush, and Diane Wender. This group recognized the need for a forum for research integrity professionals and took it upon themselves to create it. ARIO's mission is focused on creating a professional network for RIOs that includes resources to support their work in protecting and promoting research integrity.

To find out more about the organization, we interviewed one of its co-founders, Lauran Qualkenbush, RIO at Northwestern University.

What was the rationale behind forming ARIO?

Qualkenbush: Working as a RIO myself for a number of years, I rarely encountered other RIOs at professional meetings, let alone found opportunities to discuss common issues or best practices. After speaking with some colleagues at the April 2013 "ORI at 20" meeting in Baltimore, we decided to try to get RIOs together for this very purpose.

RIOs often work in isolation on highly confidential and extremely complex matters, so the simple opportunity to build networks of experienced RIOs and share resources was the fundamental benefit on which ARIO was based.

What was the response from the community to ARIOs formation?

Qualkenbush: The response was immediately positive, and the community was overwhelmingly receptive. The first meeting was hosted by Johns Hopkins University School of Medicine in 2013, before we even had a formal association; the meeting had over 80 attendees. The more we reached out to identify institutional RIOs and tell them about ARIO, the more momentum the group gained. By our second annual meeting in Chicago, we had over 100 attendees, and ARIO has continued to grow. My experience has been that as people participate in ARIO activities, they immediately recognize the benefits of engaging with a professional community dedicated to protecting the integrity of research. Additionally, regional groups took off after the Chicago meeting and have developed strong local networks of resources and contacts.

Tell us about your current membership. How many institutions are involved and how do they contribute to ARIO?

Qualkenbush: ARIO is composed of the participating RIOs, their support staff, and their counsel and does not yet have formal membership. However, the Board of Directors developed a membership structure that will be rolled out over the next year. Because this is still a grass-roots effort, "member volunteers" are responsible for all ARIO activities. Each annual meeting is hosted by a volunteer

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NEW ASSOCIATION PROVIDES RESOURCES FOR RIOS

(Continued from page 6)

institution, and regional efforts are driven by the participating RIOs. There are many opportunities for professional growth and contribution to this strong and valuable professional organization. Additionally, the Board will be putting out a call for volunteers for our standing committees to help drive new initiatives and bring more robust resources to our members. Anyone interested in becoming more involved can contact me or any Board member directly.

How is this conference different than other meetings for research administrators?

Qualkenbush: ARIO is targeted to RIOs, their staff, and their counsel. As such, the meeting content is focused on the roles that RIOs play in promoting research integrity and investigating research misconduct. Often research compliance administrators have responsibilities for multiple compliance areas. The ARIO meeting is targeted at those with a direct role in the research misconduct review processes, unlike other more general research administrative conferences that cover a variety of compliance topics. Topics covered include practical and operational discussions related to handling research misconduct allegations, presentations from federal oversight partners, discussions on the new National Academies Report on Fostering Research Integrity, case studies, and much more. Additional details and program agenda can be found online at: https://sites.google.com/ucsd.edu/ario2017/home

"...the perspectives from RIOs and their counsel are important in shaping the national agenda for tackling research integrity. Until ARIO was formed, RIOs didn't have the formal structure to contribute to the national dialogue."

How do you see ARIO evolving in the next 5 to 10 years?

Qualkenbush: ARIO will continue to grow, especially as more individuals get involved. The initial inertia from the steering group has brought us to a place where now we are really poised for others to get more involved and help develop the future of ARIO. Personally, the Midwest regional group has really solidified with strong participation from a number of institutions; however, I'm also happy to hear new people join our monthly calls almost every month. We are planning to roll out the formal member structure and institutional membership fees over the next year, and with that will come additional resources, a formal online community, and hopefully more regional activities.

Additionally, there is great potential in fostering collaborations with international research integrity networks, for example the European Network of Research Integrity Offices (ENRIO), to build collective resources and share best practices. This is something that I personally think will make a significant contribution as ARIO participates in the global research integrity dialogue.

I think we're all hopeful that ARIO will be sustainable for many years to come, and as the regulatory world evolves, we anticipate that ARIO can be nimble enough to meet those needs and that of our members.

What services does ARIO currently provide or plan to provide in the future?

Qualkenbush: ARIO is in the process of creating an outward facing website as well as a private, online member site where information can be shared securely. This will include listserv support, job postings, and other online resources. As ARIO members become more involved and the standing committees begin their work, it is expected that these resources will continue to grow.

Additionally, many regional groups are very active and have created local networks of resources and contacts for RIOs. For example, the Midwest region to which I belong hosts monthly conference calls and has created a Wiki site to share resources like

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NEW ASSOCIATION PROVIDES RESOURCES FOR RIOS

(Continued from page 7)

institutional policies, templates, and checklists. The Midwest group also has hosted annual regional meetings for the last three years in an effort to create more resources to share. The Mid-Atlantic group has hosted regional meetings and continues to host regular conference calls, and groups are beginning to form in the Southeast and West Coast regions.

The National Academies of Sciences, Engineering, and Medicine (NASEM) recently released a report entitled "Fostering Integrity in Research." The report gives 11 recommendations for handling challenges in research integrity. How do you see ARIO's role in in meeting these recommendations?

Qualkenbush: ARIO hopes to play a role in addressing the recommendations from the NASEM report. In particular, I think the perspectives from RIOs and their counsel are important in shaping the national agenda for tackling research integrity. Until ARIO was formed, RIOs didn't have the formal structure to contribute to the national dialogue. There is value in the experience and knowledge this group can provide. ARIO hopes to find ways to collaborate and contribute to the initiatives that spring from this report and welcome any opportunity to advance research integrity through working together with the many stakeholders.

Upcoming Event

Responsible Conduct of Research Instruction Workshop

The purpose of this two-day train-the-trainers workshop is to help new or inexperienced Responsible Conduct of Research (RCR) instructors to develop and implement best practices in RCR instruction. The course presenters are experienced RCR instructors and researchers who will present distinct topics, lead active discussions and exercises, and identify useful resources (case studies, short writing assignments, etc.) for a foundational understanding of RCR and the tools needed for successful RCR instruction. Particular focus will be on active learning approaches most effective for adult learners. Four topic sessions (data; misconduct; collaboration; and publication and authorship) will demonstrate effective teaching methods and illustrate positive and negative practices in the conduct of research. In addition, three sessions (pedagogy, assessment, and RCR program management) will introduce structural, practical, tactical, and strategic aspects of RCR instruction.

The next RCR workshop is scheduled for March, 2018. The location has not yet been finalized. If you are interested in participating, please contact Tracey.Randolph@hhs.gov.

Knowing Our Partners: Survey of RCR Coordinators and RIOs

The Office of Research Integrity (ORI) works closely with Research Integrity Officers (RIOs) at institutions handling allegations of research misconduct involving biomedical or behavioral research or research training supported by the Public Health Service (PHS). Likewise, ORI provides training and educational materials for institutional Responsible Conduct of Research (RCR) Coordinators who play a role in assuring that their research institution fosters a research environment that promotes the responsible conduct of research and discourages misconduct.

In early 2017, ORI surveyed a random sample of RCR Coordinators and RIOs (535 in each group, selected from institutions that have an ORI assurance) to better understand their backgrounds, roles, and responsibilities. Participants were limited to individuals representing institutes of higher education; research organizations; institutes, foundation or laboratories; and other health, human resources, and environmental service organizations. The two groups received slightly different surveys, with questions tailored to their specific activities.

Who are the RCR Coordinators and RIOs?

Of the 535 RCR Coordinators chosen for the sample, half (275) opened the email directing them to the survey link, and 135 responded to the survey, yielding a 25 percent response rate. Of the 535 RIOs chosen for the sample, half (285) opened the email directing them to the survey link, and 113 responded to the survey, yielding a 21 percent response rate.

Here is what we learned about RCR Coordinators:

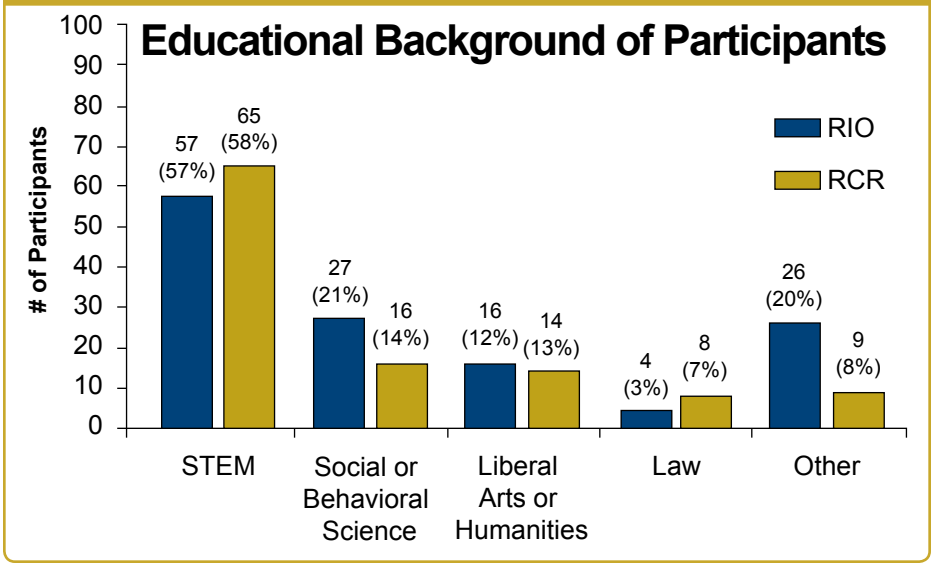
- 62% have the title of Research or Compliance Administrator
- 9% are faculty members
- 5% are academic administrators
- 23% are something "other" (e.g., grants administrator, program manager, chief scientific officer, or executive director)

Among RIOs:

- 58% are Research or Compliance Administrators
- 12% are faculty members
- 10% are academic administrators
- 20% are something "other"

These are relatively experienced professionals—41% of RCR Coordinators and 35% of RIOs have served in that role for more than six years. Moreover, the survey participants are highly educated: 44% of RCR coordinators and 58% of RIOs hold a Ph.D., M.D., D.V.M., or D.O. In each group, one in four has a master's degree. Other degrees include baccalaureates and J.D.s.

Figure 1



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KNOWING OUR PARTNERS:
SURVEY OF RCR COORDINATORS AND RIOS

(Continued from page 9)

Importantly, given the breadth of research under their purview, these professionals come from diverse educational backgrounds (see Figure 1, page 9.)

- 43% of RCR Coordinators and 58% of RIOs come from a Science, Technology, Engineering, or Mathematics (STEM) field
- 21% of RCR Coordinators and 14% of RIOs come from the Behavioral and Social Sciences
- 13% of RIOs are from the Liberal Arts/Humanities
- each group had a sprinkling of individuals with a background in law
- among those who chose "other" are individuals with backgrounds in business, accounting, finance, health care administration, health science, education, public health, business, and ethics

Institutional Roles

ORI was curious about the primary roles these professionals play at their institutions. The survey showed that a majority (60%) of RCR Coordinators are responsible for meeting the needs of the National Institutes of Health (NIH) policy on RCR instruction for their institution's trainees. However, only 30 percent are currently responsible for teaching RCR courses.

In comparison, a majority of RIOs participate in RCR instruction at their respective institutions (51% "a great deal" or "a moderate amount," 26% "occasionally," 23% "rarely" or "never").

ORI was particularly interested in the level of survey participants' involvement with research misconduct assessments, inquiries, and investigations. Overall, the survey found that participants are not often involved in such activities. Only 12 of 107 participants (11%) that stated they currently have an ongoing research misconduct assessment, inquiry, or investigation that involves PHS funding. Likewise, a clear majority of participants (81%) said that their institution has fewer than one investigation or inquiry each year, while only two participants had more than four per year. Three participants (3%) stated that they did not know how many investigations or inquiries their institution has per year. In some ways, these findings are reassuring, in that they reflect the relatively low incidence of potential or actual misconduct cases. However, the findings also reflect the need for continuous training and refresher courses for RIOs who might not encounter many cases in a given year to keep them well versed in and aware of evolving issues.

In summary, even though this was a nonscientific survey, the results give us a window into the communities of professionals who are so essential to ORI's mission and to ensuring integrity in research. ORI plans to use these findings as we consider new opportunities for training, conferences, and ongoing communications with our partners in the field. ORI thanks the institutional officials who took the time to complete the survey!

ORI Awards Four Conference Grants

The Office of Research Integrity (ORI) sought to support conferences to develop multi-disciplinary networks to build upon existing evidence-based research and stimulate innovative approaches to preventing research misconduct and promoting research integrity. ORI was especially interested in supporting conferences that lead to extramural grant applications on research on research integrity and peer-reviewed publications. In FY2017, ORI awarded four grants on conferences on reproducibility, preventing research misconduct, and plagiarism. These conferences are scheduled to take place before during FY2018.

"Plagiarism: A Conference on the Identification, Processing, Prevention and Cultural Context of Plagiarism"

John Baumann, Ph.D.

Indiana University

Abstract: Research Integrity Officers have expressed a need to enhance the understanding of plagiarism in research and identify a platform to share resources and practical tools in successfully handling research misconduct allegations of plagiarism. Indiana University's goal is to provide an innovative and interactive conference that will: 1) expand the understanding of the cultural variables which may contribute to plagiarism in research; 2) supply practical tools and resources in the handling of plagiarism allegations for Research Integrity Officers; and, 3) offer responsible conduct of research education tools that further promote the prevention of plagiarism. This conference entitled, "Plagiarism: A Conference on the Identification, Processing, Prevention and Cultural Context of Plagiarism," will include a multi-disciplinary approach involving a national steering committee that will shape the program planning, identify the subject matter experts, and present at the conference based on their own research integrity experience. Subject matter experts will be identified to provide a comprehensive analysis on plagiarism, to assist in the cultural understanding of plagiarism both from a national and international perspective. This understanding will then be utilized to expand the community's compendium of tools and resources needed for handling allegations of plagiarism and delivering the responsible conduct of research education for the prevention of plagiarism. The outcomes will be to increase attendee's knowledge and understanding of plagiarism from a cultural perspective of plagiarism, provide innovative approaches to investigate and analyze allegations of plagiarism, and design a new educational model for the prevention and education of plagiarism based on gained cultural understanding. IU will create a national steering committee made of Research Integrity Officers and Responsible Conduct of Research Educators to develop a conference proceeding document summarizing what was learned, what tools were identified, and how these tools and new understandings can be utilized to better educate our research community.

"GRID: Ghanaian Research Integrity Development"

Arthur L. Caplan, Ph.D.

New York University School of Medicine

Abstract: The overarching goal of this project is to form a multi-disciplinary network of leaders in a position to foster a culture of research integrity (RI) in those institutions producing and supporting biomedical research in Ghana and in relevant professional communities. The project will build on existing evidence and create plans for additional research to stimulate innovative approaches to preventing research misconduct (RM) and promoting RI. Strengthening the infrastructure of research integrity in Ghana will be achieved through planning and executing a two-day conference in Accra, Ghana in June of 2018 called Ghanaian Research Integrity Development (GRID). GRID will bring together approximately 40-50 leading researchers

(continued on next page)

ORI AWARDS FOUR CONFERENCE GRANTS

(continued from page 11)

and administrators with responsibility for RI from academic institutions across Ghana, national funding and regulatory agencies within the country, editorial boards and publishers of relevant journals, and other relevant stakeholdersto analyze the current state of RI and RM in Ghana, and lay the groundwork for stronger networks and governance mechanisms at the national level and within Ghanaian research institutions. A conference organizing committee consisting of researchers, educators, and administrators from Ghana and New York University (NYU) will gather and jointly analyze literature and background documents from institutions, professional societies and government in order to prioritize

"The overarching goal of this project is to form a multidisciplinary network of leaders in a position to foster a culture of research integrity"

needs, including relevant research on RI and RM in Ghana; develop a statement of aims for the conference based on the needs assessment; and identify essential speakers and invitees. Members of the organizing committee will also serve as speakers and discussion group facilitators at the conference. The project will achieve four objectives specific to Ghana: 1) describe relevant policies and procedures which support RI, 2) examine specific challenges to RI including estimated level of RM, 3) develop plans to implement emerging global RI standards within Ghanaian institutions and governance structures and 4) form a sustainable network to promote RI and prevent RM across Ghana. A white paper summarizing the state of RI in Ghana will be produced, along with two articles concerning issues of RI unique to the Ghanaian context. It is expected that this process will be relevant to other similarly situated low and middle-income countries (LMICs) that are involved in international research.

"Promoting Research Integrity in Multidisciplinary and Multi-team Based Science Initiatives"

Stephen Zacarro, PhD; Richard Klimuski, PhD; Aurali Dade, PhD

George Mason University

Abstract: Concerns around research integrity have grown exponentially in the last ten years, and the issues have begun to extend beyond examples of data fabrication and plagiarism to include more nuanced issues including failure to perform as promised, disputed claims to intellectual property ownership, the inability to replicate findings or statistical standards for research quality all of which are faced by scientists participating in multidisciplinary teams (e.g., Edwards & Roy, 2017; Head, Holman, Lanfear, Kahn, & Jennions, 2015; Mårtensson, Fors, Wallin, Zander, & Nilsson, 2016; Phillips, Wanner, Morgan, & Langdorf, 2017). These issues will be exacerbated in scientific collective research where scientists are part of multiteam systems (MTSs), as well as being part of the conventional interdisciplinary team. MTSs are made up of groups of teams, often themselves interdisciplinary in nature, that are brought together to solve problems that are significant in scale and scope (Zaccaro, Marks, & DeChurch, 2012). There are theoretical arguments and some empirical evidence to propose that by their nature scientific MTSs have the potential to give rise to unique legal and ethical challenges. Accordingly, we plan to design a workshop to bring together individuals who are actively involved in such multi-team science initiatives to act as participants. This workshop will be aimed at clarifying the nature of lapses in the operation of such complex systems when it comes to research integrity using the insights of participants derived from both their direct and indirect multi-teams experience. Using a framework developed from research on the governance of complex team systems, we will then work with participants to develop a set of specific scenarios that reflect differing levels research integrity risk. With this in hand, the remainder of the day- long

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ORI AWARDS FOUR CONFERENCE GRANTS

(continued from page 12)

workshop will be spent developing a risk mitigation checklist that can be shared and used by scientists contemplating the design of major research initiatives involving multi-disciplinary multi-team players with the goal of promoting scientific integrity in such collectives.

"Building Research Integrity through Reproducibility Conference"

Melissa Rethlefsen, MSLS, AHIP

The University of Utah

Abstract: Fostering a culture of research integrity is critical to academic institutions and to science. The myriad components of research integrity create a framework for responsible conduct of research, but also high quality research. Current research in reproducibility has largely focused on two major aspects: identifying the problem through retrospective analysis and replication studies, and proposing solutions for data and code registration, documentation, and open sharing. Training in research reproducibility methods, concepts and culture is not yet widely available, especially for established faculty and principal investigators, research coordinators, and practicing scientists. Students at both the undergraduate and graduate levels may also lack formal training, as many methods in reproducibility are learned by direct mentorship from PIs or through brief modules in more extensive courses on study design and conduct. At the University of Utah, the Spencer S. Eccles Health Sciences Library is well positioned to familiarize and build awareness among researchers on issues of reproducibility, thereby promoting and helping foster a culture of research integrity and high quality research. Recognized on campus as the go-to experts, a core group of librarian faculty teach and consult on issues of reproducibility and bias, and provide general support for a culture of replication. Specifically, this project will build on the success of their first Research Reproducibility Conference, held in 2016. They envision that this ORI-sponsored conference will bring together researchers, students and experts from diverse areas of research, education and administration to further develop educational tools and programs needed to build research integrity through reproducibility. The focus of this conference will be on finding ways to help individual researchers make research true. They intend to model the conference on the successful 2016 program and schedule. The proposed conference will include two keynote speakers, a panel of local experts, a panel of journal editors, breakout sessions for posters and papers, and ample time for networking and discussions. A call for posters and papers will be made at the start of 2018, and submissions will be peer-reviewed prior to acceptance. They expect that repeated exposure to concepts of research integrity and reproducibility will influence and change how participants approach the research process over time. The conference will build awareness of research reproducibility and provide a forum for discussion and opportunities for researchers on varying levels to network and build collaborative research relationships.

"The conference will build awareness of research reproducibility and provide a forum for discussion and opportunities for researchers on varying levels to network and build collaborative research relationships."

Tools Can Help Detect Misconduct, but Culture Change is Needed to Improve Integrity

By Chris HJ Hartgerink, Tilburg University

All the sciences face misconduct at some point, so preparing for it is necessary. Not only in how to deal with it when discovered, but also by addressing the issue head on and deterring people from ever committing misconduct. Trust still plays a large role in many facets of science (regretfully so it often supersedes verification), which ultimately might lead to neglect of obvious problems in publications by editors and reviewers.

Upon asking editors and reviewers, Bornman and colleagues (2008) identified that editors and reviewers in their sample did not use any criteria related to potential falsification or fabrication in making their decisions. As such, it is relatively easy for unreasonable effects to seep into the literature, because it is simply not part of the evaluation process. For example, Nick Brown recently tweeted a test statistic from a peer-reviewed social psychology paper that implies a 99.999979% explained variance due to an experimental manipulation, which is unheard of in the social sciences. I know of several other papers that passed peer review but that did not stand up to the curious investigation of graduate students.

But the main question is: why don't editors and reviewers use any criteria related to potential falsification or fabrication in their decision process? I can only speculate, but I can imagine it is an interaction between mediocre knowledge of how to spot problems, the subsequent confidence in the correctness, combined with the severe consequences it can have for the author in question. Providing tools to editors, reviewers, and also readers to better spot problems and which are validated can be effective in increasing the confidence and empowering editors, reviewers, and readers to raise potential issues.

The U.S. Office of Research Integrity has generously funded my research on such statistical tools to help detect potential problems, but more is needed than just tools for editors, reviewers, and readers to raise issues. There currently is still very much a culture of fear in science—a fear for pointing out potential mistakes in other people's work, malicious

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In FY2016, ORI awarded Chris H.G. Hartgerink a grant to research and develop a statistical tool to detect research misconduct.

The Value of Statistical Tools to Detect Data Fabrication

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Abstract: We aim to investigate how statistical tools can help detect potential data fabrication in the social- and medical sciences. In this proposal we outline three projects to assess the value of such statistical tools to detect potential data fabrication and make the first steps in order to apply them automatically to detect data anomalies, potentially due to data fabrication. In Project 1, we examine the performance of statistical methods to detect data fabrication in a mixture of genuine and fabricated data sets, where the fabricated data sets are generated by actual researchers who participate in our study. We also interview these researchers in order to investigate, in Project 2, different data fabrication characteristics and whether data generated with certain characteristics are better detected with current statistical tools than others. In Project 3 we use software to semi-automatically screen research articles to detect data anomalies that are potentially due to fabrication, and develop and test new software forming the basis for automated screening of research articles for data anomalies, potentially due to data fabrication, in the future.

TOOLS CAN HELP DETECT MISCONDUCT, BUT CULTURE CHANGE IS NEEDED TO IMPROVE INTEGRITY

(continued from page 14)

or unintended. In the open-source programming community, finding and pointing out (potential) mistakes is encouraged and welcomed by the community because it is about achieving a collective goal: good software. Why not in academia?

Academia has the tendency to punish people who raise potential mistakes, because the system is highly individualistic for a seemingly collective undertaking. Not only do whistleblowers end up with the short end of the stick, but also those trying to point out simpler mistakes. When I collaborated with PubPeer to post 50,000 reports on rounding errors in statistical results, some claimed I accused them of fraud or that all discussion about potential mistakes should take place behind closed doors so the authors could correct their mistakes out of view. Why not have these discussions out in the open, to increase participation, learning moments, and verifiability to prevent further mistakes?

The scientific system currently still dissuades scientific progress because publications are the measure of success (amongst others), and pointing out mistakes could lead to a retraction or corrigendum, which would harm a researcher's publication record and their reputation. At least, that's how it is often perceived in such a reputation based system. In other words, if the system is rewarding doing the wrong thing (i.e., avoiding handling mistakes), how can we expect people to do the right thing (i.e., correct mistakes)?

Despite this tendency of punishing people who raise potential issues or simple mistakes, some people are trying to do the right thing. Elizabeth Bik is one example. She recently live-tweeted some of her investigations on falsification in images, which exposes her to severe criticism but, in the end, is for the good of science. Moreover, she sets an example of how discussion could take place outside of conventional media and in a civilized manner. John Carlisle, who discovered the Fuji case and now applied his method to thousands of clinical trials, got called back for being indiscreet in a recent reply, whereas he was only investigating the plausibility of results—not accusing anyone of fraud.

"Providing tools to detect problems will not solve academia's problems—for that we need to collectively change our culture to be more open to the discussion of potential mistakes and inclusive of varying perspectives to facilitate that discussion."

Providing tools to detect problems will not solve academia's problems—for that we need to collectively change our culture to be more open to the discussion of potential mistakes and inclusive of varying perspectives to facilitate that discussion. This will not only help detect malicious problems, but it will also facilitate the discussion of unintentional mistakes and correcting those. But in order to do achieve such a healthy academic environment, we need to start rewarding ethical behavior first and systematically.

Research Misconduct Case Summaries

Case Summary: Chegini, Nasser

Based on the report of an investigation conducted by the University of Florida (UF), the prior corrections in the scientific record noted below, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Nasser Chegini, retired as a Professor in the Department of Obstetrics and Gynecology, UF, engaged in research misconduct in research supported by National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant 2 R01 HD037432.

ORI acknowledges that the following papers were retracted as a result of the institution's investigation:

(1) J Clin Endocrinol Metab 88(10):4967-4976, 2003. Retraction in: J Clin Endocrinol Metab 100(1):318, 2015 Jan.

(2) Reprod Biol Endocrinol 1:125, 2003. Retraction in: Reprod Biol Endocrinol 13:25, 2015 Apr 3.

(3) J Clin Endocrinol Metab 88(3):1350-1361, 2003. Retraction in: J Clin Endocrinol Metab 100(1):318, 2015 Jan.

(4) Hum Reprod 21(10):2555-2563, 2006. Retraction in: Hum Reprod 30(1):249, 2015 Jan (Epub 2014 Nov 6).

(5) Mol Hum Reprod 12(4):245-256, 2006. Retraction in: Mol Hum Reprod 20(12):1258, 2014 Dec (Epub 2014 Nov 13).

(6) Mol Hum Reprod 13(11):797-806, 2007. Retraction in: Mol Hum Reprod 20(12):1259, 2014 Dec (Epub 2014 Nov 13).

(7) Reprod Sci 15(10):993-1001, 2007. Retraction in: Reprod Sci 21(10):1326, 2014 Oct.

(8) J Cell Mol Med 12(1):227-240, 2008. Retraction in: J Cell Mol Med 19(10):2512, 2015 Oct.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying data that were included in: J Reprod Immunol 73(2):118-29, 2007 (hereafter referred to as "JRI 2007"). Specifically, ORI found that Respondent falsified data points and standard errors of the mean in bar graphs plotting matrix metalloprotease expression or activity in the following figures of JRI 2007:

- Figures 2A, 2B, 2C
- Figures 3A, 3B, 3C
- Figure 4B
- Figure 5C
- Figure 6B
- Figures 7A, 7B, 7C
- Figure 8, middle left panel and lower right panel

Dr. Chegini entered into a Voluntary Settlement Agreement with ORI, in which he voluntarily agreed to the following, beginning on July 12, 2017:

(1) Respondent has not applied for or engaged in U.S. Public Health Service (PHS)- supported research since 2012; Respondent has no intention of applying for or engaging in PHS-supported research or otherwise working with PHS; however, if within five (5) years of the effective date of the Agreement, the Respondent receives or applies for PHS support, the Respondent agreed to have his research supervised for a period of five (5) years from the date of his employment in a position in which he receives or applies for PHS support and agreed to notify his 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 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

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CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

RESEARCH MISCONDUCT CASE SUMMARIES

(continued from page 16)

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;

(2) Respondent agreed that for a period of five (5) years beginning on the date on which the Respondent receives or applies for PHS support, 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 five (5) years, beginning with the effective date of the Agreement; and

(4) as a condition of the Agreement, Respondent will request that J Reprod Immunol 73(2):118-29, 2007 be retracted.

Case Summary: Mirchandani, Alec

Based on the report of the inquiry conducted by Florida Atlantic University (FAU), the Respondent's admission, and analysis conducted by ORI, ORI found that Mr. Alec Mirchandani, former post-baccalaureate research volunteer in the Center for Complex Systems and Brain Sciences, Florida Atlantic University (FAU), engaged in research misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grant 1 R15 MH099590-01A1.

ORI found that Respondent engaged in research misconduct by knowingly and intentionally:

(1) fabricating the results of the T-maze behavioral experiment for control mice, (2) falsifying the laboratory and vivarium entry logs in an effort to cover up his actions, and (3) reporting the fabricated and falsified data to his laboratory supervisors.

Specifically, ORI found that Respondent knowingly and intentionally:

- fabricated the results that he recorded for the T-maze behavioral experiment in three of the five TMZ control mice on the laboratory data sheets and white board on fourteen (14) of the sixteen (16) eligible days in June 2016, to make it appear as though he had conducted the experiments
- falsified the animal transfer logs on twelve (12) of the sixteen (16) eligible days in June 2016, to make it appear as though he had conducted the experiments
- fabricated the times he recorded on the laboratory data sheets on fourteen (14) of the sixteen (16) eligible days in June 2016, to make it appear as though he had conducted the experiments
- incorporated and recorded the fabricated and falsified data with his previous data in his laboratory notebook and reported the results to his laboratory supervisor and principal investigator, such that the experimental control data (five animals) for experiments conducted from January 2016-June 30, 2016, were not accurately represented

Mr. Mirchandani has entered into a Voluntary Settlement Agreement with ORI, in which he voluntarily agreed, beginning on June 29, 2017:

(1) that if within two (2) years from the effective date of the Agreement, Respondent receives or applies for U.S. Public Health Service (PHS) support, Respondent agrees to have

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RESEARCH MISCONDUCT CASE SUMMARIES

(continued from page 17)

his research supervised for a period of one (1) year, beginning on the date of his employment in a position in which he receives or applies for PHS support, and agrees to notify his 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 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 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) 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 one (1) year, beginning with the effective date of the Agreement.

Case Summary: Sauer, Frank

NOTE: On June 22, 2017, the ALJ's recommended decision became the final agency decision.

View Decision: *Office of Research Integrity v. Frank Sauer, Ph.D.*

Based on evidence and findings of an investigation conducted by the University of California, Riverside (UCR), the Office of Research Integrity's (ORI's) review of UCR's Research Misconduct Investigation Report, the Report of Investigation by the National Science Foundation (NSF) Office of Inspector General, additional evidence obtained by ORI during its oversight review of UCR's investigation, and independent analyses conducted as part of ORI's oversight review, ORI found that Dr. Frank Sauer, former Associate Professor of Biochemistry, UCR, committed research misconduct in research supported by the following National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH) grants:

- R01 GM073776
- R01 GM066204
- Images that were falsified and/or fabricated were presented in the following publications and grant applications.
- Gou, D., Rubalcava, M., Sauer, S., Mora-Bermúdez, F., Erdjument-Bromage, H., Tempst, P., Kremmer, E., & Sauer, F. "SETDB1 is involved in postembryonic DNA methylation and gene silencing in Drosophila." PLoS One 5(5):e10581, 2010 (hereafter referred to as "PLoS One 2010").
- Sanchez-Elsner, T., Gou, D., Kremmer, E., & Sauer, F. "Noncoding RNAs of trithorax response elements recruit Drosophila Ash1 to Ultrabithorax." Science 311(5764):1118-1123, 2006 (hereafter referred to as "Science 2006").
- Maile, T., Kwoczynski, S., Katzenberger, R.J., Wassarman, D.A., & Sauer, F. "TAF1 activates transcription by phosphorylation of serine 33 in histone H2B." Science 304(5673):1010-1014, 2004 (hereafter referred to as "Science 2004").
- National Institute on Drug Abuse (NIDA), NIH, grant application R21 DA025703-01
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant application R21 DK082631-01
- NIDDK, NIH, grant application R01 DK082675-01
- NIGMS, NIH, grant application R01 GM073776-06A1
- NIGMS, NIH, grant application R01 GM085229-01
- NIGMS, NIH, grant application R01 GM085303-01

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CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

RESEARCH MISCONDUCT CASE SUMMARIES

(continued from page 18)

- NIGMS, NIH, grant application R01 GM085303-01A1

ORI found by a preponderance of the evidence that the Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating images in seven (7) submitted NIH grant application and three (3) published papers by manipulating, reusing, and falsely labeling images.

Specifically, the Respondent falsified and/or fabricated images representing controls or experimental results for in vitro interactions between RNA and proteins, co-immunoprecipitation ("co-IP") assays, histone methytransferase ("HMT") or kinase assays and related stained SDS-PAGE gels, and reverse transcription-polymerase chain reactions ("RT-PCR") in the following grant applications and publications.

(1) The image in Figure S4, Science 2006, representing the in vitro interactions between RNA and specific proteins, was used in similar assays to represent results with other sets of protein-RNA interactions in Figure 9, R21 DA025703-01, Figure 9, R21 DK082631-01, and Figure 9, R01 DK082675-01, and again in R01 GM085229-01, Figure 11C.

(2) The image in Figure 1A, R01 GM085303-01, representing a co-IP assay from the Drosophila cell line S2, was manipulated and used in Figure 1B of the same grant application to represent a different co-IP assay from Drosophila embryonic extracts.

(3) The image in Figure 8A, R01 GM085303-01A1, representing an SDS-PAGE gel for an in vitro HMT assay, was used previously in Figure 1d in a manuscript submitted to Nature in 2005 to represent an SDS-PAGE gel from an unrelated experiment for an ubiquitination assay.

(4) The image in Figure 1E, R01 GM085303-01 and Figure 1D, R01 GM085303-01A1, representing stained SDS-PAGE for an HMT assay, was used in Figure 1b, Nature 419(6909):857-862, 2002, to represent an HMT assay with different experimental conditions, and also was used in Figure 1B, Science 2004, to represent stained PAGE for an in vitro kinase assay.

(5) The image in Figure 1C, R01 GM085303-01 and Figure 1B, R01 GM085303-01A1, representing an HMT assay, was manipulated and used to represent an HMT assay with different experimental conditions in Figure 1E, R01 GM085303-01 and Figure 1D, R01 GM085303-01A1, and also was used to represent another unrelated HMT assay in Figure 2 (right panel) in R01 GM085303-01.

(6) The image in Figure 2 (right panel) in R01 GM085303-01 representing an HMT assay was used in Figure 1B, PLoS One 2010 to represent an HMT assay with different experimental conditions.

(7) The image in Figure 6B, R21 DA025703-01, Figure 11B, R01 GM085229-01, Figure 6B, R01 DK082675-01, and Figure 6B, R21 DK082631-01, all representing RT-PCR experiments for transcribed ncRNAs, was used in Figure 13, R21 DK082631-01 and Figure 13, R21 DA025703-01 to represent RT-PCR experiments for transcription for different ncRNAs.

(8) The image in Figure 10C (right half) in R01 GM073776-06A1, representing transcription of endodermal genes from embroid bodies, was manipulated and used in Figure 10C (left half) in the same grant application to represent the transcription of mesodermal and ectodermal genes.

Science 311(5764):1118-1123, 2006 was retracted in: Science 344(6187):981, 2014. Science 304(5673):1010-1014, 2004 was retracted in: Science 344(6187):981, 2014. Nature 419(6909):857-862, 2002 was retracted in Nature 521(7550):110, 2015.

ORI issued a charge letter enumerating the above findings of research misconduct and proposing

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CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

RESEARCH MISCONDUCT CASE SUMMARIES

(continued from page 19)

HHS administrative actions. Dr. Sauer subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute these findings. The parties filed cross-motions for summary judgment. On May 22, 2017, the ALJ recommended to the Assistant Secretary for Health that summary judgment be granted in favor of ORI. On June 22, 2017, the ALJ's recommended decision became the final agency decision. Thus, the research misconduct findings set forth above became effective, and the following administrative actions have been implemented, beginning on June 22, 2017:

(1) Dr. Sauer 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, through July 27, 2020, the end date of his government-wide debarment, which was imposed by NSF; and

(2) ORI will send a notice to PLoS requesting retraction or correction of PLoS One 5(5):e10581, 2010 (PMID: 20498723) in accordance with 42 C.F.R. § 93.411(b).

Case Summary: Baughman, Brandi

Based on Respondent's admission and analysis conducted by ORI, ORI found that Dr. Brandi M. Baughman, former Intramural Research Training Awardee, National Institute of Environmental and Health Sciences (NIEHS), NIH, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK101645 and the NIEHS, NIH, Postdoctoral Intramural Research Training Award (IRTA).

ORI found that falsified and/or fabricated data were included in eleven (11) figures in PLoS One 11(10):e0164378, 2016 (hereafter referred to as "PLoS One 2016").

ORI found that Respondent falsified and/or fabricated data and text published in PLoS One 2016, in Figures 2, 3, 4, 5, 6, 8, S1, S2, S3, S4, and S5, by claiming that a screening strategy of the kinase focused libraries, PKIS and 5K, was performed, when original data do not exist to support the claims. Respondent also claimed that three (3) inhibitory compounds for the inositol phosphate kinase, PPIP5K, were identified from the 5K library, when these compounds, UNC10112646, UNC10225354, and UNC10225498, were not part of the data set for the 5K library. Specifically, Respondent falsified and/or fabricated the characterization of the inhibitor compounds in:

- Figures 2 and 3 results for Z'-factor, %CV, signal:background ratio, and a 10-point dose response titration experiment for inhibitor UNC10225354
- claims in the text of PLoS One 2016 that eight molecules from the PKIS library and fifteen molecules from the 5K library inhibited PPIP5K activity by >50%
- Figure 4D results for the inhibition by UNC10112646, UNC10225354, and UNC10225498, in dose response assays against the kinase domain of PPIP5K
- Figures 5A and 5B results for isothermal titration calorimetry (ITC) assays for quantifying intermolecular interactions between PPIP5K and the inhibitors, UNC1011264 and UNC10225498, and Figure S5 for UNC10225354
- Figure 6 results for the analysis of the mechanisms of inhibition of PPIP5K by UNC10112646 and UNC10225498
- Figures 8A and 8B results for high performance liquid chromatography (HPLC) analysis for the effects of UNC10112646 or UNC10225498 on PPIP5K activity and IP6K activity
- Figures S1-S4 for experimental results further characterizing UNC10112646, UNC10225498, and other inhibitors, when the results were not supported by the experimental records.

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CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

RESEARCH MISCONDUCT CASE SUMMARIES

(continued from page 20)

As a result of Respondent's admission, NIH recommended that the PLoS One 2016 paper be retracted.

Dr. Baughman has entered into a Voluntary Settlement Agreement with ORI, in which she voluntarily agreed:

(1) to have her research supervised for a period of three (3) years beginning on May 17, 2017; Respondent agreed to ensure that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which 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 she will not participate in any PHS-supported research until a plan for supervision is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that for a period of three (3) years beginning on May 17, 2017, 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;

(3) to exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on May 17, 2017; and

(4) as a condition of the Agreement, to the retraction or correction of PLoS One 11(10):e0164378d, 2016 (PMID: 27736936).