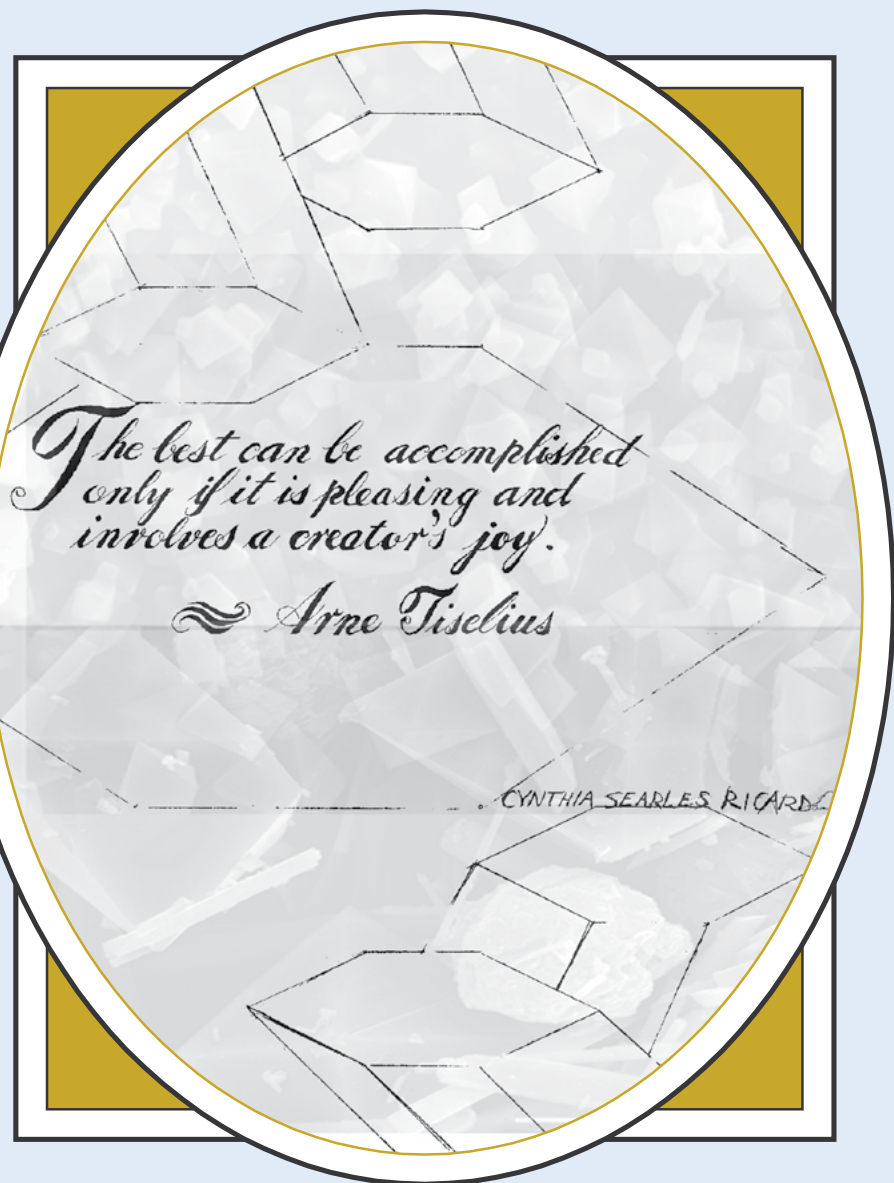




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Original illustration by ORI staff member, Dr. Cynthia Ricard



MESSAGE from the DIRECTOR



I have been fortunate to attend some very thought-provoking workshops and conferences in the past few months and would like to reflect here on what I have learned. As always, I continue to be impressed with the positive energy and innovative thinking coming from various cohorts of the research community. It is such a privilege and a pleasure to be engaged in the work of ORI.

The topic that has grabbed my attention at these events is correcting the scientific literature, from amendments to corrections to retractions. I attended the University of Utah [Research Reproducibility 2016](#) conference on November 14, hosted by the Spencer S. Eccles Health Sciences Library. The Priscilla M. Mayden Lecture was presented by Hilda Bastian, scientist and editor at the National Center for Biotechnology Information of the National Institutes of Health. Her talk focused on the skills, practices, and accessibility that provide the foundation of good science. She also discussed the value of post-publication review and the role PubMed plays in incorporating post-publication comments or expressions of concern. In fact, I was delighted to learn that the National Library of Medicine will in 2017 implement a new pair of [linking elements to tag notices](#) that express concern about an article. This is an extremely important advancement that permits institutions to notify journals of problems with data in published papers, allows journals to express concern, and provides notice of the concern to the public almost immediately. This is an important change, and one that we applaud.

Perhaps the most uplifting quote of the day was from Dr. Ioannidis: “Science is the best thing that has happened to humans.”

The featured speaker, David Moher, senior scientist at Ottawa Hospital Research Institute and associate professor at University of Ottawa, presented on reporting guidelines, an important aspect of publication science. Dr. Moher was instrumental in the develop-

ment of the CONSORT and PRISMA statements—as well as other reporting guideline initiatives. He presented a sobering talk on how reporting guidelines can be effective and facilitate replication; yet they are generally under-utilized, and their use by authors is under-rewarded.

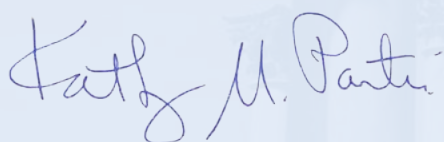


MESSAGE from the DIRECTOR

Finally, the Clifford C. Snyder, M.D., and Mary Snyder Lecture was presented by John P.A. Ioannidis, professor of medicine at Stanford. Dr. Ioannidis gave a scholarly, in-depth lecture on the culture of academic research and the reproducibility that impacts specific disciplines, titled “How Can Universities Make More Published Research True/Reproducible?” This was a very elegant talk on heterogeneity of results and the difficulties of measuring signal to noise in science. Dr. Ioannidis has played a pivotal role in research reproducibility and has published on some of the worst of the worst scientific practices. His lecture, which has been [archived](#) (as have the others), is definitely worth viewing! Perhaps the most uplifting quote of the day was from Dr. Ioannidis: “Science is the best thing that has happened to humans.”

The take-home message I walked away with is affirmation that scientific research and communication comprise a complex endeavor with many important stakeholders, all of which play a critical role today in research reproducibility and research integrity. This is a fast-moving time.

The take-home message I walked away with is affirmation that scientific research and communication comprise a complex endeavor with many important stakeholders, all of which play a critical role today in research reproducibility and research integrity. This is a fast-moving time. Academic institutions across the country (I have attended similarly innovative and powerful conversations at Stanford and Columbia Universities in the past month) and globally are seeking to have important conversations and try new ways to promote research integrity. It is clear that there are many promising developments. 🌱





RESEARCH INTEGRITY NEWS



The Association of Research Integrity Officers (ARIIO), now formally incorporated, held its fourth annual meeting in New York City on September 26 to 28, 2016. Hosted by Memorial Sloan Kettering Cancer Center, the three-day conference had 120 attendees and was the largest gathering to date. Attendees included Research Integrity Officers

(RIOs) and their general counsel from small and large United States institutions and medical centers, as well as representatives from Australia, Canada, and Norway. The sessions included updates and dialogue with several federal oversight agencies, including the HHS Office of Research Integrity, National Science Foundation Office of Inspector General, Office of Human Research Protections, Office of Laboratory Animal Welfare, and the Veterans Health Administration. From ORI, the director, division directors, and two scientist investigators participated. Plenary and breakout sessions addressed important RIO-related issues; for example, plagiarism, forensic techniques, research misconduct in clinical research, the reckless standard for findings of research misconduct, research misconduct metrics, facilitating research misconduct committees, and perspectives from journal editors. The meeting also included an optional post-conference workshop

Got Questions? Ask ORI.

HOW DO I MAKE AN ALLEGATION OF RESEARCH MISCONDUCT?

I'm the RIO, and I'm not sure what to do about...?

Is it okay to use ORI's educational materials in my RCR course?

I reported misconduct then my contract wasn't renewed. Is this retaliation?

How do I use ORI's forensic image tools?

I think someone plagiarized my work. What do I do?

I REPORTED MISCONDUCT BUT HAVEN'T HEARD ANYTHING. WHAT'S HAPPENING?

If we can't answer your question, we can refer you to the people who

Email us at AskORI@hhs.gov if you have questions about research integrity.

ori.hhs.gov

@HHS_ORI

#ORledu

Hosted by Memorial Sloan Kettering Cancer Center, the three-day conference had 120 attendees and was the largest gathering to date.

on reproducibility and transparency in science. ARIIO 2017 will be hosted by the University of California from September 25 through 27, 2017, in San Diego, California. RIOs interested in participating in future ARIIO events can contact nu-ori@northwestern.edu to be added to the email distribution.

ORI is providing these new infographics in a scalable PDF format to allow universities and other research institutions to download them and print posters for display on campus and in laboratories. This and other infographics can be downloaded from: <https://ori.hhs.gov/blog/ori-releases-infographics-series>



Short Course on RCR Instruction: A new trainer-of-the-trainer project of the Office of Research Integrity

Kenneth D. Pimple, Ph.D.¹

The purpose of the Short Course on RCR Instruction (SCoRCRI, pronounced “sorcery”) project is to help new or inexperienced responsible conduct of research (RCR) instructors to develop and implement “best practices” in RCR instruction. The course presenters, comprised of experienced RCR instructors and researchers, will define distinct topics, lead active discussions and exercises, and

The seed of SCoRCRI was sown at the Listening Session called by Kathy Partin, the then-new director of ORI, in late April 2016. Dr. Partin invited about 20 RIOs and RCR instructors as well as key ORI personnel, including Susan Garfinkel, director of investigative oversight, and Zoë Hammatt, director of education and integrity.

I had the good fortune to be part of the meeting and was even more fortunate when Dr. Partin asked me



identify useful resources (case studies, short writing assignments, etc.) that will provide a foundational understanding of RCR and the tools needed for successful RCR instruction. The active learning approaches most effective for adult learners will be prominent.

to develop the new workshop. Having directed the Teaching Research Ethics workshop for 20 years, I was delighted by the opportunity to work with ORI. One of my first suggestions was to not use “boot camp,” largely because I was sure the similarity of the two titles would create unnecessary confusion.

In 2006, the Office of Research Integrity (ORI) started a project called RIO Boot Camp (Wright and Schneider 2010) as “part of a major ORI initiative to support and to professionalize the role of Research Integrity Officers,” or RIOs (ORI 2016). Until now, there was no analog for instructors of RCR.

We started with a skeleton plan and quickly began recruiting national and international leaders in RCR instruction and research on science integrity to provide individual input on the planning.

As we started inviting potential planning members, we also solicited their individual views and insights. I invited each prospective member individually by email and followed up with a scheduled telephone

¹ Dr. Pimple is a subject matter expert in RCR who works as a contractor for ORI.

discussion. In this recruitment stage, one-on-one communication was dominated by concerns about the influence, for good or bad, of the PHS and NSF regulations requiring certain funded researchers to receive RCR instruction, overlooked problems in the state of science, the general quality of RCR instruction and programs in the United States, and other varied topics.

Our next step was to convene a 90-minute teleconference of the planning members, with 12 of the 14 members participating, from all four time zones of the continental United States. The members were lively, opinionated, informed, supportive, critical (in the best sense), disciplined, and humorous.

We planned to have four teleconferences, but the discussions were so productive and efficient that the second teleconference was the last. I continued collecting individual input from two to four members at a time by email and kept all the members up to date.

As of this writing, the schedule, speakers, venue, and date have been determined, but the event has not been officially announced.

The event will total 15½ hours over two days. Each day will begin with an introduction and end with a


discussion. During the second session on day one, two experts will cover the NIH and NSF regulations concerning RCR instruction. Most of the sessions will have two or three presenters, and only two of the 16 presenters will be involved in more than one substantive session.

The rest of the sessions will include four content-focused sessions and two meta-focused sessions, each succinctly titled with a single word. The former will cover data, misconduct, collaboration, and authorship. The latter will cover pedagogy and assessment.

The short course will take place from April 5 to 6, 2017, at the HHH building in Washington, DC. Those interested in attending should contact Tracey.Randolph@hhs.gov

for more information. Registration will be limited to 20-35 participants. There will be no registration fee.

ORI "RIO Boot Camp." <http://ori.hhs.gov/content/rio-boot-camp> verified November 30, 2016.

Wright, D.E., and Schneider. P.P. "Training the Research Integrity Officers (RIO): The Federal Funded 'RIO Book Camps' Backward Design to Train for the Future." *Journal of Research Administration* 41(3):99-117, 2010. <http://eric.ed.gov/?id=EJ945951> verified November 30, 2016. 

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Disclaimer

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Quest for Research Excellence Conference Planning

On September 22, 2016, the Office of Research Integrity (ORI) invited experts in research misconduct and promoting research integrity to assemble at the Tower Building in Rockville, Maryland, to provide individual input on the possible content of the upcoming Quest for Research Excellence conference, which is scheduled to take place in August 2017. Individual attendees brought to the discussion a deep knowledge of RCR, research misconduct, legal proceedings associated with misconduct, and current publication practices.

The day-long conversation was aimed at identifying broad topics that would be of interest to the research community. The attendees discussed a variety of possible topics, including:

- ▶ The boundaries between falsification/fabrication/plagiarism and questionable research practices (QRPs)
- ▶ Conflicts of interest in science
- ▶ Retractions, corrections, and publication issues
- ▶ Various federal agencies involved with research misconduct activity
- ▶ Communicating science in 2017
- ▶ International collaborations
- ▶ The tension between needs for transparency and confidentiality in misconduct proceedings
- ▶ Pressures that result from changing scientific environment (Science has changed, and as a result, there are emerging QRPs)
- ▶ Reproducibility in science (NIH devised reporting guidelines in 2014 for rigor and transparency – there is a role for universities and labs as part of this process)
- ▶ Open science and post-publication review
- ▶ Pressures on social sciences

One compelling concept was to create an interactive session in which the attendees work through a complex research misconduct case study involving many of the aforementioned themes.



ORI is providing these new infographics in a scalable PDF format to allow universities and other research institutions to download them and print posters for display on campus and in laboratories. This and other infographics can be downloaded from: <https://ori.hhs.gov/blog/ori-releases-infographics-series>

ORI is greatly appreciative of the individual input from the community – their energy and their ideas. The next step will be for ORI to develop plenary sessions that include as many of the suggested topics as possible during the two-and-a-half day conference. ORI is committed to soliciting abstracts for posters and presentations from the research community. The conference will be co-hosted by PRIM&R and George Washington University (GWU) and will likely be held on the GWU campus. Stay tuned for information regarding the dates and registration.

Perspectives from Inside ORI's Division of Investigative Oversight

By Kathi E. Hanna

In late November I spent an afternoon in ORI's Division of Investigative Oversight (DIO) talking to investigators about their current jobs and the paths they took to get to them. I was interested in their perspectives on ORI's mission and how they handle the obligation to ensure fairness, manage complex cases, and pursue just conclusions in the oversight of the investigative process. What struck me the most was their unanimous agreement on the importance of their mission—that their principal role is to protect Public Health Service funds as well as to protect good scientists and weed out bad ones. They also are abundantly aware that a finding of research misconduct can be harmful to a career and that even an investigation that does not find research misconduct can cast a pall over the accused and his or her institution.

DIO's investigators are trained scientists. The investigators I spoke with included an immunologist, a chemist, a neuroscientist, and a molecular biologist. They came to ORI through circuitous and variable routes—from funded faculty positions, postdoctoral fellowships, foundation program offices, government laboratories, and grants administration. Consequently, individually and collectively they have been exposed to the many facets of the scientific enterprise.

Importantly, DIO investigators are experienced scientists and have conducted their own research. They appreciate the pressures that exist for those pursuing scientific careers, that is, having a good idea that can be tested, validated, and published, which then fuels further good ideas that might benefit the

public and their field, lead to more funding, and advance promotions and recognition. As one member of the staff said, "at the heart of science is truth and truthfulness. If your data are wrong, can't be trusted, or can't be validated, you have nothing. The whole research system operates on the need to get to as close to the truth as possible."

One investigator walked me through ORI's processes for handling allegations, which also are described on the office's [website](#) in greater detail. Currently,

What struck me the most was their unanimous agreement on the importance of their mission—that their principal role is to protect Public Health Service funds, as well as to protect good scientists and weed out bad ones.

there are seven investigators on staff, each handling as many as 10 to 30 ongoing cases at any given time. They rotate the weekly assignment of managing incoming queries and allegations, which are answered and logged. Some of these queries involve issues not within ORI's jurisdiction, which are referred to the appropriate office—for example, the Office for Human Research Protections or the Office of the Inspector General—or involve technical and/or procedural clarifications of ongoing cases. Others are potential research misconduct allegations. Individuals who allege that research misconduct has occurred are referred to as complainants, and those accused of research misconduct are referred to as respondents.

If a complainant reports credible and specific information about potential research misconduct to ORI, the allegation is logged and tracked. Complainants can include research collaborators, journal editors, institutional officials, peers, grant reviewers, watchdog organizations, bloggers, or anonymous. Complainants also may report the alleged misconduct directly to their institutional officials, journals, and funding agencies rather than to ORI.

Specific and credible allegations, as determined by the DIO investigator's initial assessment, are



RESEARCH INTEGRITY NEWS

then referred to the institution where the alleged misconduct occurred. DIO staff rely heavily on the research integrity officers (RIOs) at institutions to follow their institutional policies for handling allegations of misconduct according to their assurance with ORI and report findings, but DIO also serves as a critical resource in helping those institutions locate expertise, technologies, or strategies for analyzing evidence. For each case at ORI, an investigator may need to review a significant amount of substantial documentation, such as grant applications, publications, computer files, research data, slides, letters, emails, memoranda, transcripts, and summaries of interviews. Some cases are straightforward and are addressed quickly, particularly if the accused individual confesses to misconduct. Others can involve hundreds of allegations, numerous parties, numerous institutions, and understandably, a significant amount of stress and friction.

The DIO investigators told me that what makes their work most challenging, but also most interesting, is the fact-finding and investigatory work required to determine whether misconduct actually has occurred, as opposed to bad science or an honest error. They told me that dissimilar fields offer similar opportunities to skew, obscure, hide, conflate, or distort data, so in some ways, investigators are likely to see the same types of behaviors across disciplines. On the other hand, dissimilar fields also can have dissimilar opportunities for misconduct; for example, through selective reporting of results based on favoring a particular research hypothesis, unique experimental designs used only in a narrow field, or use of highly specific equipment, such as imaging. Thus, investigators have to understand the science and the scientific methods at the center of the case.

The investigative staff members I spoke with have been in the office for anywhere from six to thirteen

years, so they have enough time behind them to respond to my questions about trends. One interesting unintended consequence of the growth in interdisciplinary, multidisciplinary research is the increase in the size of research teams and number of names on a publication. This makes it more complex for investigations to track the sources of data and where evidence is located. Another development that has changed the nature of their work is easy desktop electronic access to publications, images, image manipulation software, and simple comparative search software that can detect language similarities. These capabilities not only make it easier to falsify or fabricate data, but also enable those with suspicions to do some of their own detective work. As a result, the office is receiving more allegations;

however, the average number of findings of misconduct and number of debarments has remained steady. Nevertheless, there is some concern about the increase in anonymous whistle blowing, made easier by increased online access to papers published globally and the ready availability of online tools for discerning potential plagiarism and image manipulation. If the claims are credible, which many are, all the better. However if they are frivolous or in bad faith, it increases the volume of work for DIO investigators and diverts resources from more serious and plausible cases.

Importantly, DIO investigators do not take sides in institutional investigations, and they are not involved in institutional decisions. Institutions determine the actions they will take, and if the government elects to pursue a case, DIO investigators assist the ORI director in recommending appropriate administrative actions, such as debarment from federal funding. Many cases are settled with the respondents. If a case cannot be settled, DIO investigators provide assistance to help determine the government's next action and assist with potential appeals that may be made by respondents. *(continued on page 19)*

Another development that has changed the nature of their work is easy desktop electronic access to publications, images, image manipulation software, and simple comparative search software that can detect language similarities.

NEWS RESEARCH INTEGRITY NEWS

ORI Releases New Video Case Studies on the Responsible Conduct of Research

The ORI Division of Education and Integrity (DEI) has released a new series of video case studies to address integrity issues faced by those involved in the research endeavor.

The goal of this project was to create short, meaningful videos that could serve as a springboard for discussion about conducting research responsibly. We hope that the videos, as well as the infographics

that are displayed throughout this newsletter, will supplement existing teaching tools used by the research community.

The videos follow the story of Dr. Jeff Thompson and his budding research lab. Amit, a postdoctoral fellow, and Ashley, a graduate student, are navigating challenges inherent to working in a competitive research environment. By touching on topics that affect researchers at all levels of their careers, such as mentoring, authorship and publication practices, data integrity, and possible research misconduct, these scenarios encourage viewers to consider how to make responsible choices at every turn.

The following video case studies are now available:

- ▶ “Choosing the Right Lab”
- ▶ “Reproducibility or Luck? The Struggle to Get Results”
- ▶ “Data Cherry Picking”
- ▶ “The Misuse of Placeholders”
- ▶ “To Proceed or Not to Proceed Without Raw Data?”
- ▶ “Crossing the Line into Misconduct”
- ▶ “I Wrote It, Why Re-Write It?”
- ▶ “When Authorship Gets Personal”
- ▶ “How Impact Factors Impact You”
- ▶ “Biased Peer Review or Flawed Methodology?”
- ▶ “You Suspect Research Misconduct. Now What?”

The production of the videos was a year-long project requiring research and creative development by Penelope Theodorou and Madeline Rooney, ORI’s education and communication fellows, and Dr. Julia Behnfeldt, ORI’s presidential management fellow, in collaboration with the entire ORI staff.

The video case studies can be viewed and downloaded from the ORI website: <https://ori.hhs.gov/videos/case-study>



ORI is providing these new infographics in a scalable PDF format to allow universities and other research institutions to download them and print posters for display on campus and in laboratories. This and other infographics can be downloaded from: <https://ori.hhs.gov/blog/ori-releases-infographics-series>

World Conference on Research Integrity 2017

Research regulations and accepted research practices vary internationally and across professional organizations. Even when there is consensus on vital elements of research integrity, policies to promote and enforce research integrity can vary widely. The World Conferences on Research Integrity have emerged as an international forum for the study and discussion of means to promote responsible research. They began as an experimental extension of ORI's conference program to Europe in 2006, spearheaded by ORI (Consultant Nicholas Steneck, Director Chris Pascal, and Director of the Division of Education and Integrity Larry Rhoades), the European Science Foundation (Chief Executive Bertil Andersson and Consultant Tony Mayer), and other entities, such as the Organization of Economic Cooperation and Development and the International Council of Science. The first World Conference on Research Integrity (1WCRI) convened in Portugal in 2007. Its primary goal was to bring researchers and research leaders together to discuss what could be done to promote research integrity and respond to the growing number of misconduct cases in research. 1WCRI included 275 participants from 47 countries.

2WCRI was planned for Singapore, and funding was provided by Singapore Management University; the Agency for Science, Technology, and Research (A*STAR); and other organizations. Funds were made available for modest travel grants to participants from disadvantaged countries, an important first. 2WCRI was a worldwide event involving more than 340 participants from 51 countries. The [Singapore Statement on Research Integrity](#)

emerged from 2WCRI, and has been translated into 27 languages.

3WCRI was planned in partnership with the National Research Council Canada, and took place in Montréal in May 2013. 3WCRI continued the practice of previous conferences by involving government officials, publishers, and leaders in policy and education and recruited researchers who were actively studying the responsible conduct of research. Attendance at 3WCRI grew to 366 participants from 44 countries. The [Montréal Statement on Research Integrity in Cross-Boundary Research Collaborations](#) emerged

as a companion document to the Singapore Statement, and is now available in 14 different languages.

Rio de Janeiro, Brazil, was selected for 4WCRI, bringing the World Conferences to South America, with the goal

of encouraging participation from countries that had previously been underrepresented. Representatives from 58 countries participated, with 474 total conference participants. The theme of 4WCRI was "Research Rewards and Integrity: Improving Systems to Promote Responsible Research." Delegates illustrated the ways in which integrity initiatives might diverge from earlier models, by emphasizing the importance of local context to strategy.

5WCRI is scheduled for late May 2017 in Amsterdam, marking the 10th anniversary of the WCRI effort. ORI's division director, Zoë Hammatt, played a significant role on the Planning Committee, which met in Washington, DC, in 2016. Plans and registration forms are posted on the World Conferences [website](#). The overarching theme of 5WCRI is promoting transparency and accountability in research. We look forward to the upcoming reveal of the full program.

The World Conferences on Research Integrity have emerged as an international forum for the study and discussion of means to promote responsible research.

Japan Agency for Medical Research and Development Opens New Office in Washington, DC

As described in the ORI September 2016 newsletter, Dr. David Hudson, research integrity officer at the University of Virginia, and Dr. Susan Garfinkel and Ms. Zoë Hammatt, ORI's division directors, had the honor of accepting an invitation from the Japan Agency for Medical Research and Development (AMED) to present at the inaugural Research Integrity Conference in Tokyo last June (see page 29 of the September 2016 issue: <https://ori.hhs.gov/newsletters>). To further strengthen partnerships around integrity and research development, AMED established a Washington, DC office on November 1, 2016.

AMED engages in research and development (R&D) in the field of medicine, providing funding to promote integrated medical R&D in Japan, from basic research through practical application, and establishing and maintaining an environment for this R&D (<http://www.amed.go.jp/en/aboutus>).

The Washington, DC office will work to advance broad collaboration with research institutes and funders in the field of biomedical R&D, working across the spectrum from basic research to clinical trials and promoting integrity in the research enterprise. The office seeks to exchange information on research policy and best practices as well as to build stronger connections with the medical research community in Japan.

Contact the Office:

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 AMED Washington, DC Office
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 Washington, DC 20036
 Tel.: 202-804-4056
 Fax: 202-804-4057
 Email: contact@amedjp-us.org

EVERYONE PLAYS A ROLE IN RESEARCH INTEGRITY
 — A "PUBLISH OR PERISH" CASE STUDY —

There are many reasons someone might engage in research misconduct — such as inadequate training and oversight, personal and professional stress, and fear of failure.

One potential driver of research misconduct is the pressure to "publish or perish." Let's look at how this is affecting Bob, a young scientist, and how his environment may be a contributing factor.

The U.S. Department of Health and Human Services (HHS) defines research misconduct as:

FABRICATION, FALSIFICATION, or PLAGIARISM in proposing, performing, or reviewing research, or in reporting research results.¹

PERSONAL LEVEL


Bob is falsifying data

Bob is working hard to publish his research. He is facing a tight deadline and his experiments are not yielding desirable results. He feels that the only way to meet his deadline is to falsify his data.

What leads him to commit research misconduct?

13

HHS makes about 13 findings of research misconduct a year.



HELLO
Bob

INTERPERSONAL LEVEL

Bob's lab is under pressure to publish

Dr. C, Bob's boss, places unreasonable demands on the lab team to produce publishable results. Dr. C is busy and rarely reviews the raw data. Without any oversight, Bob easily falsifies his data.

What can his lab supervisor do to reduce this pressure?

72%


In 45 cases of research misconduct committed by trainees, 72% of supervisors had not reviewed the source data.²

INSTITUTIONAL LEVEL

The university rewards academic publications and grants

Dr. C needs more publications to earn tenure. Her department chair requires Dr. C to secure grant funding to maintain her lab. These pressures distract Dr. C from her mentoring responsibilities in the lab.

What can the university do to reward responsible research?



RESEARCH COMMUNITY LEVEL

The research community reinforces the pressure to "publish or perish"

Bob, Dr. C, and their institution are part of a broader research community. They all face the competitive pressures generated by their peers, funding sources, journals, and academic societies.


What can the research community do to change this norm?


The pressures scientists face are perpetuated at every level.

What can you do to promote integrity from your place in this system?

Citations:
¹ For the HHS definition of research misconduct, see 42 C.F.R. § 93.103.
² Wright, D. E., Tian, S. L., Combs-Burns, J. B. (2008). Mentoring and Research Misconduct: An Analysis of Research Mentoring in Civil and Environmental Engineering. *Science and Engineering Ethics*, 14, 203-209.
³ Getting Published in Nature: The Editorial Process. (2016). Retrieved March 17, 2016. <http://www.nature.com/nature/collections/gettingpublished>

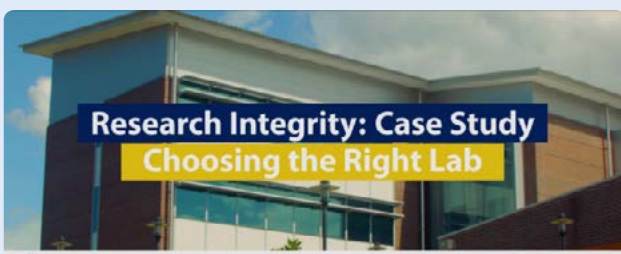
ori.hhs.gov | @hhs_ori | askORI@hhs.gov







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Research Integrity: Case Study
Choosing the Right Lab



ori.hhs.gov | @hhs_ori | askORI@hhs.gov





Experience the issues that arise from being in a small lab through the eyes of a new principal investigator (PI), a postdoctoral fellow, and a graduate student.

Page 12



ORI's Newest Staff: Tracey Randolph



Tracey Randolph, new program analyst at ORI

If you have attended one of ORI's conferences, workshops, or RIO boot camps, you may already know Tracey Randolph, a program analyst in the director's office at ORI. Her responsibilities include planning and implementing meetings and conferences as well as handling the onboarding process for ORI's new hires. She is

an ORI team member with a focus on excellence and success for every member of our team.

Prior to joining ORI, Tracey was a contractor. She worked as project manager on the logistics contract and records management specialist and FOIA records-keeper on the subject matter expert contract. Tracey is most proud of the general fund of knowledge and skills she acquired in the varied positions she held prior to joining ORI, including working in human resources, accounting, marketing, research, and general office management.

Tracey was born in Illinois. She needs to be on her best behavior, because her mom is a pastor at a church in Savannah, Georgia. In her free time, Tracey enjoys making scented candles, body lotions, and soaps. She is married and has a teenaged daughter.

We treasure Tracey's sunny disposition and the many things she does to make the workplace cheerful, above and beyond her assigned duties, from distributing birthday cards for signatures to helping plan our office celebrations.

POSSIBLE RED FLAGS OF RESEARCH MISCONDUCT

- TIME**
 - Usable data are only generated when there is a pressing deadline
 - Experiments are completed faster than usual
- RESULTS**
 - Data are too good to be true
 - Findings can't be replicated by others in the lab
- LACK OF TRANSPARENCY**
 - Raw data can't be produced when requested
 - Research materials and protocols are kept hidden
 - Work is mostly done when no one else is around

If you suspect research misconduct
contact your institution's Research Integrity Officer or ORI at AskORI@hhs.gov

ori.hhs.gov @HHS_ORI #ORledu

ORI is providing these new infographics in a scalable PDF format to allow universities and other research institutions to download them and print posters for display on campus and in laboratories. This and other infographics can be downloaded from: <https://ori.hhs.gov/blog/ori-releases-infographics-series>

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ORI's Newest Staff: Scott Moore



Scott Moore, new deputy director of ORI

What will you do at ORI? In other words, what is your job?

I am the deputy director for ORI—in large part, my role is to assist the director in the administration of the office, standing in for her whenever she is unavailable, and acting as a sounding board for exploring a variety of policy questions. I will be doing quite a bit

of the behind-the-scenes operational work making sure that ORI staff have what they need to carry out the mission, but I hope to do some outreach in the research community whenever possible.

What did you do immediately before joining ORI?

I came to ORI initially on a detail from the National Science Foundation (NSF) Office of Inspector General (OIG). In government-speak, that is when one agency loans an employee to another, often for a special project or because of particular expertise. At NSF OIG, I was an investigative scientist, a position similar to DIO's scientist investigator, and my primary function was handling allegations of research misconduct (RM) for NSF. In a relatively small OIG like NSF's, everyone wears multiple hats, so we were all crossed-trained to investigate a broad range of allegations beyond RM. In my case, I worked RM cases as well as financial fraud and cybercrime cases, either as the lead investigator, the case attorney, or the digital evidence specialist. My most interesting cases were the hybrid cases that commingled many of these issues into a single matter. Along the way, I took on some administrative/

operational roles in the office, working closely with the NSF IT staff.

How long have you worked in the government? In ORI? In academic world? In research world?

I was with NSF OIG a little over 13 years and arrived there within a year of finishing law school and passing the bar. Before that, I completed a Ph.D. in chemistry and spent a little time as a post doc to finish up projects and hand off my lab administrative duties. I often miss the lab environment, but I would not change the path I have taken since leaving. I was lucky and found my dream job where cutting-edge science and law come together in very interesting and unexpected ways.

What do you think are the differences in working in the government versus academic institution? Any advice to those making a switch from academia/research to administration and policy work?

I often compare government agencies to universities that have no students. Both are pretty bureaucratic environments and can be frustrating if you are not prepared or paying attention. Not all bureaucracies are alike. My advice is to ask a lot of questions to build context from multiple vantage points and to keep asking questions to challenge your assumptions. My transition into government was smooth because I had a good foundation in administrative law, which governs how we conduct our mission. Perhaps the biggest mistakes I see academics/researchers make in the transition to government could be avoided by recognizing the enormous wealth of information and support they have in their administrative support staff. Engaging with your research peers is generally easy and essential for collaboration, but engaging with your support staff will really help you understand how things get done with less headache.

“In a relatively small OIG like NSF's, everyone wears multiple hats, so we were all crossed-trained to investigate a broad range of allegations beyond RM.”



What are you most proud of accomplishing in your time before ORI?

Professionally, I am most proud of the work I did helping scientists apply legal concepts like assessing the levels of intent or the distinction between copyright infringement and plagiarism. The law enables us to do the work we do—it is really inextricable from handling a RM case. In my experience, academics and researchers often prefer to focus only on the science and minimize their involvement with legal aspects of cases. I was very active in formulating NSF OIG’s current approach to explaining legal concepts to individual university investigation committees without influencing their deliberations. Demystifying the federal policy and NSF processes for investigation committees was always satisfying. They generally appreciated knowing that someone on the government side understood what they were going through and were there to listen.

Can you please discuss how mentors fit into your prior life. Being mentored by others and mentoring others? Any thoughts about mentoring in general – like what it takes to be a good mentor?

I have been extremely lucky throughout my training and career to have had some great mentors and to have mentored some remarkably stellar students and interns. From my days as an undergrad, the whole idea of life-long learning and the importance of quality mentorship have been ingrained in me. It is not so much about making that network connection as it is finding a sounding board and genuine honest—sometimes brutal, but sincere—feedback. The best mentors are the ones that will advise you, let you make your own mistakes, and help you learn from them. I can only hope that my mentees have benefited as much as I have from interacting with them.

You worked with many individuals and leaders over the years. We wonder if you have some thoughts about developing relationships with other disciplines, institutional officials, or government officials.

In general, I try to kindle those relationships by asking lots of questions, listening to the answers, and checking my assumptions at the door. Everyone has expertise and value to add. Building strong relationships with the funded community and our federal partners is vital to the work we do. There are so many disciplines involved in handling misconduct allegations, picking up the pieces afterward, and learning from cases. The privacy and confidentiality concerns that we juggle in handling cases can make the flow of information difficult at times. My practice has always been to be candid with the institutional officials and leaders about what my boundaries are and to stick to those boundaries.

Could you please describe your ideas/vision of ORI and your early goals for ORI?

Much of my current role is helping the director and staff with strategic planning and charting the short and long term goals of the office. One of the factors that led to my detail at ORI—and ultimately to my applying for the position—was a desire in both offices to build even stronger collaborative ties between ORI and NSF OIG. My first case as a rookie investigator for NSF OIG was a joint jurisdiction case with ORI. The differences in our authorities were intriguing and inspired me to look critically at all the implementations of the OSTP federal-wide policy. We have evolved a lot in our collaborative process since then, and I am eager to be involved in its continuing evolution. The research enterprise moves quickly, so we need to be vigilant in reviewing our policies and regulations for relevancy and effectiveness.

Scott is also an accomplished concert bassoonist and worked with a marching band. He enjoys baking, especially perfecting recipes for pies. And yes, he bakes the crust from scratch, too! He is a photographer and successfully competed to have his photographs gracing the covers of several NSF OIG semi-annual reports. 🍪

Auto Formatting in Spreadsheet Software Introduces Errors in Research Reports

In a paper published in *Genome Biology* on August 23, 2016, Assam El-Osta, Mark Ziemann, and Yotam Eren provide data illustrating that approximately one-fifth of papers with gene lists supplied in the Microsoft Excel spreadsheet file format contain flawed gene name conversions due to automated formatting functions included within the software (1). This occurs when, for formatting purposes, Excel “auto-converts” gene symbols to erroneous calendar dates. Additionally, RIKEN identifiers are shown to be falsely converted to floating point numbers. This problem was highlighted more than a decade ago by Zeeberg et al. (2), although Microsoft has not publicly addressed the issue or offered an option to disable this feature.

The methodology in discovering these errors began with identifying 18 journals published between 2005 and 2015. In this analysis, 35,175 supplementary Excel files were examined, 7,467 of which were gene lists. If the first 20 rows of a column contained five or more gene symbols, a regex (regular expression) search was applied. In total, 987 supplementary files from 704 published articles contained errors. In sum, 19.6 percent of all gene lists examined contained errors. In addition, 166 affected .XLS files contained no other identifying features, such as accession numbers or genomic coordinates, thereby rendering the original gene names unknown.

As for limitations in scope of the research, the researchers noted that only vertical gene name lists were examined; horizontal gene name lists were likely present but not accounted for within the 18 chosen journals. Furthermore, programmatically accessed pay-walled supplemental files were unable to be included for analysis.

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Linear-regression estimates illustrate that gene name errors have increased at an annual rate of 15 percent over the last five years. The researchers describe a workaround to spot if gene names have been erroneously converted. This method involves

copying the gene list to a new Excel spreadsheet and then sorting the column. The authors also have offered researchers the scripts that they used for this research so that they, too, can quickly scan for errors in existing gene lists.

1. Ziemann M., Eren Y., & El-Osta A. “Gene name errors are widespread in the scientific literature.” *Genome Biology*, 17:177, 2016. DOI: 10.1186/s13059-016-1044-7.
2. Zeeberg B.R., Riss J., Kane D.W., Bussey K.J., Uchio E., Linehan W.M., et al. “Mistaken identifiers: gene name errors can be introduced inadvertently when using Excel in bioinformatics.” *BMC Bioinformatics* 5:80, 2004.

Science Follows Up On the Fate of the Debarred

Can a scientist recover and return to a research career after being charged with research misconduct? How do administrative actions that are imposed on the guilty change behaviors or career pathways? In 2016, *Science* magazine researched roughly two dozen debarred scientists who were later able to resume research (1). Jeffrey Mervis' report of that effort notes that although ORI and the National Science Foundation (NSF) share a mission with regard to promoting and protecting research integrity and protecting government interests, ORI publicly shares most of the details of their investigations, while NSF does not. Of those debarred by either ORI or NSF whom *Science* could track down, few were willing to talk, citing distrust or the ongoing pain of the experience. None was willing to be named, but several gave permission for *Science* to contact senior university administrators.

The concept of a formalized rehabilitation to academic research is relatively new. In 2013, James DuBois received a \$500,000 NIH grant to form a program that aims to rehabilitate researchers (see our September 2016 newsletter). 39 researchers have participated to date, but only one of three attendees has actually committed misconduct; most are there for lesser offenses, loosely defined as "sloppy research." Dubois noted that some participants are sent at the direction of their institution with no detail of their misconduct. This is a matter of preserving the institution's reputation, said Dubois.

In investigating scientists who were debarred by ORI or NSF, *Science* details three individuals and the unique circumstances of their rehabilitation:

Dr. X, of the University of Texas Health Science Center, was discovered to have committed plagiarism and falsification of data on an NIH grant application. He promptly admitted guilt and was debarred from NIH funding for one year. Concurrently, he was forced to sit in on the institution's mandatory research ethics course for graduate students. After that, Dr. X was chosen to be a section leader and tasked to write

a paper in both English and his native language on why plagiarism in research was unacceptable. He subsequently went on to receive tenure and become a respected member of the faculty.

Dr. Y, a tenured professor at the University of Central Florida, had a different fate than Dr. X. NSF debarred him for two years for applying to multiple grants with the same application. He initially appealed the judgment, and during the two-year debarment, relied on industry funding. To signify conformity to NSF's demands, the University of Central Florida did not renew Dr. Y's appointment to a prestigious chair position. But once he acknowledged his misconduct and his debarment ended, he returned to the chair position and went on to receive future NSF grants.

Dr. Z, from Rowan University, plagiarized information in two grant applications in 2012. Rowan University punished him in multiple ways. His promotion to full professorship was delayed (at a cost of roughly \$60,000 to him, over his lifetime). In addition, he was barred from using travel and professional development funds. He was appointed to the university's academic integrity committee in hope that he would be continuously exposed to the committee's message on ethical research practices. For three years after debarment, all of his grant proposals and paper submissions were monitored. Since then, he has reclaimed federal grants and is in good standing with colleagues.

Despite the fact that, in some cases, universities are willing to rehabilitate researchers guilty of past misconduct, these individuals still are not entirely in the clear, writes Mervis. Moreover, concludes Mervis, in a field with limited financial resources, some grant makers are not willing to give those charged with research misconduct a second chance.

References

1. Mervis Jeffrey. "After the fall." *Science* 354 354(6311):408-411, 27 Oct 2016. doi: 10.1126/science.354.6311.408


CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

Compliance Review Procedures

The following summary was developed in response to questions raised by institutional officials and others regarding the specific regulatory requirements, as well as the process developed and utilized by the Office of Research Integrity (ORI) to address various compliance issues that occur during the course of an institutional misconduct proceeding. This summary is intended to provide general information regarding compliance review procedures and should not be relied on as a substitute for familiarity with the federal laws and regulations applicable to research misconduct, including 42 U.S.C. 289b and 42 C.F.R. Part 93.

Relevant Law and Regulation: 42 USC 289b and 42 CFR Part 93

Key feature – Institutions receiving Public Health Service (PHS) research funds have primary responsibility for the handling of research misconduct allegations. ORI conducts oversight at the completion of the institutional process.

Institutional Responsibility:

Institutional Assurance: The responsible institutional official must assure on behalf of the institution that the institution:

- (1) has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct, and
- (2) complies with its own policies and procedures and the requirements of this part. (§93.301(b))

Compliance Review Protocol – Two Part Review

A compliance review is usually initiated because of inadequacies in the institutional process noted primarily during the Division of Investigative Oversight (DIO) oversight review.

Part 1. Review of institutional research misconduct policies and procedures. DIO and the Division of

Education and Integrity have developed a template to crosscheck the requirements of the PHS regulation with the provisions of the institutional misconduct policy (this checklist will be released very soon).

Part 2. Review of the institutional investigation file to examine the institution's adherence to the requirements of the PHS regulation in the conduct of an inquiry and investigation.

Typical Compliance Issues: (ori.hhs.gov/problem-areas-processing)

- (1) The initial allegations are handled by the laboratory director rather than by immediately informing the RIO
- (2) Inadequate sequestration
- (3) Lack of appropriate expertise in inquiry and investigation
- (4) Lack of properly conducted and annotated interviews
- (5) Institution often fails to pursue new allegations uncovered in the inquiry or investigation process
- (6) Institution often does not provide support to whistleblowers
- (7) Inquiry and investigative reports are often poorly documented
- (8) Institutions do not handle admissions well
- (9) Research records are not properly retained
- (10) Institutions could do a better job of providing guidelines to senior staff on their mentoring skills and responsibilities
- (11) Policies and procedures are outdated; improper use of student disciplinary procedures
- (12) IRB committees often fail to recognize and properly refer research misconduct matters

CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

Less Typical Compliance Issues:

- (1) Bad faith allegations
- (2) Lack of effort to restore reputations
- (3) Including non-research misconduct issues in institutional review
- (4) Overlapping responsibilities of the vice president for research – may conduct inquiry, be on investigation committee, be decision maker
- (5) Common ORI Compliance Actions:
 - i. Place the institution on a special review status (more frequent reporting to ORI)
 - ii. Require the institution to take specific corrective actions that address deficiencies

Examples of Institutional Corrective Action Plans:

- (1) A recommendation that an institution develop a protocol for the forensic analysis of computer hard drives as well as other electronic storage devices to properly test and otherwise examine this media to ensure that all recoverable data and other relevant evidence are properly retrieved.

- (2) A recommendation that a plan be developed to ensure that all faculty and staff are made aware of the institutional requirements to immediately report any suspected research misconduct to the RIO. Effective initiatives may include revisions to faculty, staff, and student handbooks, voluntary and/or required presentations, classes, or seminars on the topic, and the distribution of relevant materials, advice, and instructions via the institution’s website, email, or other means of general communication.
- (3) A recommendation to assess all collaborative arrangements between that institution and independent research entities to ensure that in cases where PHS research support is involved, the collaboration is structured in a manner to guarantee compliance with the requirements of the PHS regulation, either through the insistence that the research partners acquire an assurance of compliance with ORI, or formally agree to cooperate with the institution in the handling of any research misconduct allegation. ⚠

PERSPECTIVES FROM INSIDE ORI’S DIVISION OF INVESTIGATIVE OVERSIGHT

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I asked each investigator what advice they had for the research community to avoid accusations or findings of misconduct. They all acknowledged that much misconduct has a pervasive behavioral aspect to it; that is, for whatever reasons, a researcher feels compelled to falsify or fabricate data, or to copy someone else’s work. Those types of behaviors and stressors can be found in other occupations—consider white collar crime—and are difficult to anticipate in any given individual. However, the consequences of misconduct for science, and even the public health, can be substantial. Their simplest advice for preserving integrity in science is to “keep all of your data for your own protection.” Honest errors,

poor study design, or failure to appreciate critical variables and document them are not following best practices of science, but may not necessarily rise to the level of research misconduct as defined by federal regulation. These types of errors can be better ascertained by investigators, who are working to ensure justice, if the data are available and accurately reported.

One investigator also had advice for those who are thinking of making an allegation: “If you have specific and credible evidence to support the suspicion, report it. The integrity of the research enterprise depends on people speaking up.” ⚠

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