THE OFFICE OF RESEARCH INTEGRITY®

NEWSLETTER

US Department of Health and Human Services
Office of the Secretary, Office of the Assistant Secretary for Health

September 2016 | Volume 23, No. 3

ORI'S NEWEST INFOGRAPHIC

"5 Ways Supervisors Can Promote Research Integrity" infographic is now available for download. This is the first of many new educational resources that ORI plans to release in the future! Keep your eye on our Twitter feed for the most current release information.

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MESSAGE from the DIRECTOR

For the past several months I have been on a listening tour, meeting with as many different members of the research community as possible. I have met with Research Integrity Officers (RIOs), Responsible Conduct of Research (RCR) teachers and researchers, journal editors and publishers, lawyers, members of federal agencies who have responsibility for misconduct processes or RCR education, science advocacy organizations, and representatives from institutions conducting Public Health Service (PHS)-funded research. The community has been very open and willing to share its ideas with ORI, and I have learned an incredible amount from these conversations. I would like to share with you some of what I heard.

First, it was delightful to hear positive feedback on so many ORI activities. Many people complimented our Division of Investigative Oversight (DIO) staff, led by Susan Garfinkel, PhD, for serving as an open and accessible resource for technical support to RIOs who are handling misconduct cases at their institutions. They remarked that our ORI team creates a "culture of support," with genuinely hands-on advice, rather than just a "culture of compliance," where staff merely recite and enforce the regulations. Similarly, I heard a lot of positive feedback about the RIO boot camps that ORI co-teaches with members of the Association of Research Integrity Officers (ARIO) professional organization. The research community also was very enthusiastic about the conferences that ORI co-sponsors with research institutions as well as the conferences funded by ORI "Research on Research Integrity" conference grants. ORI has been involved in these activities for many years, very successfully, and we certainly will continue our involvement in years to come.

Folks responded positively when I told them we were currently filling vacancies in both our investigation and education divisions. Some institutions volunteered that they would benefit if ORI staff could travel to them at the initiation of big cases to provide guidance to their staff and to faculty committees on technical and procedural matters. The community also said that it would like ORI to publish white papers on technical aspects of research misconduct cases, including forensic methods, understanding reckless intent, and navigating the process for retractions at different points in the research misconduct investigative process.

During my listening tour, I kept hearing that institutions are seeking new and topical RCR material. Well, that's great news, because our Division of Education and Integrity, led by Zoë Hammatt, JD, MPhil., has been working hard on producing new infographics, case studies, and video vignettes for the RCR community to use in their classes. (Did you see our newest infographic, "5 Ways Supervisors Can Promote Research Integrity"?) I am really excited about the new material that DEI plans to release over the next few months. Our stakeholders also are seeking guidance on the best ways to deliver RCR instruction, including the best course content. In fact,

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these conversations have led ORI to propose an RCR instructional workshop, which we hope to offer in spring 2017.

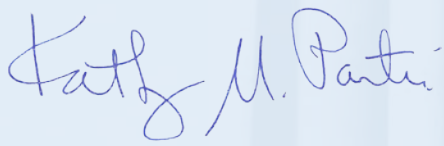
I also heard that the community is looking for evidence that specific interventions (types of RCR instruction or mentoring) in graduate education are effective in promoting research integrity (and possibly in reducing misconduct) and is asking if the ORI "Research on Research Integrity" grant program should focus on this need. We need to think about how best to accomplish the goal of measuring specific outcomes in RCR education and appreciate your ideas.

People told me they want ORI to continue publishing data on misconduct activity cases so by learning more about the causes of and factors influencing misconduct, we can do a better job of preparing trainees for a future in basic and/or clinical research. So, we are working hard on updating our data and providing fresh, new charts and plots that you will be able to download from our website and use in your RCR courses. Also we were happy to hear that you appreciate ORI's communication efforts through blogs, social media, and our newsletter, which provides a window into what is going on in our part of the research world.

Finally, both federal and non-federal stakeholders have told us they perceive a lack of harmony between the research misconduct policies and guidelines of various funding agencies, which they find frustrating. Some have asked whether we think it is time to revisit our 2005 regulations on research misconduct, given the evolution of research practices and methods over time. That would be a very significant undertaking, but it might be something we will consider down the line.

I see my listening tour as an ongoing process, so I want you to know I will always welcome feedback and new ideas from the research community. As a result of what I've heard so far, I feel confident that ORI is ready to move forward and start formulating its new strategic plan for the future. We have some pretty interesting ideas of our own, too! We hope to fold it all together into an exciting and innovative roadmap, which we look forward to sharing with you.

Please use askORI@hhs.gov to tell me what you think.



Research Integrity and Sensitive Populations: Gulf Coast Conference

February 25–26, 2016, University of West Florida, Pensacola, Florida

The principal investigator for this project was Dr. Carla Thompson, Professor, Graduate Educational Research and Statistics and Director, University of West Florida Community Outreach Research and Learning (CORAL) Center.

Working group discusses research integrity and sensitive populations during Gulf Coast Conference in February 2016.

The overarching goal of the Research Integrity and Sensitive Populations: Gulf Coast Conference was promoting research integrity and preventing research misconduct, specifically related to social science researchers and professionals conducting research with sensitive populations or topics. This working conference, funded by ORI partnered with the University of West Florida, consisted of 67 participants aimed at developing protocols and directives for researchers working with sensitive populations. The Gulf Coast region of the United States has a strong presence of sensitive populations for conducting research (elderly and aging individuals, homeless adolescents and veterans, hurricane and oil spill victims, military personnel, special needs groups, Autism and Alzheimer's Disease patients, healthcare workers, children in schools with sports, and many other special groups). The Gulf Coast Conference consisted of three major components: (1) four national keynote speakers, who highlighted "Human Subjects Protection: History and Importance for Sensitive Populations," "Aging Populations: Sensitivity Concerns," "Research Integrity and Veterans," and "Children and Poverty: Sensitivity Concerns"; (2) three breakout working groups, filled each day, aimed at developing characteristics and protocols for researchers working with sensitive populations: Research Integrity and Healthcare, Research Integrity and Military, and Research Integrity and Special Needs; (3) a 12-week online component whereby all conference participants were enrolled in a virtual space provided by the university for extended work on the three major areas of healthcare, military, and special needs sensitive populations. Fall 2016 registers more than half of the conference participants continuing the charge of the online and virtual meetings with the task of completing a collaborative monograph of the conference reflections, perspectives, and outcomes authored by multiple contributors and a paper submission to the American Association of Behavioral and Social Sciences Research Conference, scheduled for February 2017.

Keeping the Pool Clean: Prevention & Management of Misconduct-Related Retractions

July 20–22, Colorado State University
Fort Collins, CO

In July, Colorado State University hosted a three-day conference funded in part by an ORI grant, bringing together a diverse group of more than 80 attendees and 18 speakers. Speakers from federal agencies, universities, journals, researchers, and others offered various perspectives on the public perception of retraction notices. Over the first two days, two distinct themes emerged from the talks with respect to retractions: their use in cleaning misconduct from the literature, and their use in explaining why the retractions were necessary. Highly publicized retractions in response to misconduct findings were described from several different viewpoints, including those of both ORI

and the National Science Foundation (NSF) OIG, the two agencies involved in the underlying investigations. The balancing of privacy interests for Respondents/Witnesses/Complainants and the public interest in the details of these cases plays out at the federal level as well as in the institution human resources system. Many in the publication and research community asserted a desire for more detailed information to come out of these processes that would resemble a combination of ORI's Federal Register notice and NSF's detailed (but redacted) investigation reports. There was also a discussion on the systemic drivers of research misconduct and the challenges researchers face in the university environment, with practical suggestions for researchers from a quality assurance professional. Approximately 20 people attended the guidance document session on July 22, and a small working group will collaborate to develop a guidance document.

Best Practices of Biomedical Research: Improving Reproducibility and Transparency of Preclinical Research

June 9–10, 2016, National Library of Medicine, Bethesda, MD

Reproducibility of biomedical research, which is the ability to conduct projects that lead to the same results multiple times, was the focus of the interactional conference sponsored by the National Insitutes of Health (NIH). The speakers focused on the challenges of reproducibility, ethics and institutional responsibility, open science and sharing and their potential impact, scientific rigor, and best practices for reproducible research.

Of particular relevance to ORI is the issue of whether research misconduct also contributes to irreproducibility. Jon Lorsch, Director of the National Institute of General Medical Sciences, said it was a mistake to think research misconduct was not a component of the reproducibility problem, although the extent it might play is unknown.

When Science Goes Right!

In two separate incidents that got the community talking, published papers were challenged by other scientists. The data sets were released so they could be re-evaluated. This collaboration led the original authors to correct the literature and simultaneously describe the consultation that led to the correction. See the story details in Retraction Watch: http://retractionwatch.com/2016/05/20/structural-biology-corrections-highlight-best-of-the-scientific-process/

NIH Publishes Update: Availability of Resources for Instruction of Responsible Conduct of Research

On July 29, 2016, NIH released a new notice that revises NOT-OD-10-019 to provide currently active websites for resources on RCR. Of particular note, the notice provides the revised NIH Research Training website, which includes additional information on instruction in RCR. The NIH Research Training website has links to a great page on the Office of Intramural Training & Education: For Trainees Outside the NIH. In addition, the notice provides a link to the National Academy Press 3rd edition of On Being a Scientist, which is available as a free PDF.

Interview with Michael Lauer, MD Director Extramural Research, NIH

Background

Six months ago, Dr. Michael Lauer accepted the position as the new deputy director for extramural research at NIH. He started at NIH in 2007 as the director of the Division of Prevention and Population Science at the National Heart, Lung, and Blood Institute (NHLBI), and from 2009 to 2015, he served as the director of the Division of Cardiovascular Sciences at NHLBI.

Dr. Lauer received his MD from Albany Medical College in 1985, followed by an internship, residency, and clinical fellowship in medicine (cardiology) in the Harvard Medical School system. Then, from 1993 to 2007, he was a professor of medicine, epidemiology, and biostatistics at Cleveland Clinic's Lerner College of Medicine of Case Western Reserve University.

His research interests have focused particularly on clinical cardiovascular epidemiology, comparative effectiveness, and biostatistics. Dr. Lauer also has been actively involved in and a strong advocate of human subjects protection.

Interview

Q: We know you will be deeply involved in funding and policy issues as the new extramural research director. We wonder what attracted you to take on this huge responsibility to lead this effort.

I was attracted to it because it is data driven. It is like the Framingham study that I worked on years ago. I learned then that you gain insights when you examine the data. This will help us know the best way to fund future research.

For instance, we have learned by doing an analysis of who gets funding that the competition for funds continues to increase but our award level remains the same. We have 27,500 unique investigators each year, but the number of scientists applying has grown from 60,000 to 90,000 over the past 13 years. Thus, it is easy to understand the hypersensitivity of scientists who are worried about funding.

The article can be found at https://nexus.od.nih.gov/all/2016/05/31/how-many-researchers/

Looking at our own data also helps us to think of things we could do better. We have learned that peer review in the study section used to award 60%, whereas now, it is 15%. Hence, the review panel in the past only had to sort the good from the very poor applicants; now, it is much harder to determine. This led us to decide to award 10 points' advantage to early stage investigators to encourage them to apply. This approach to give an advantage to beginning investigators has been successful in bringing in investigators for the first time who are also successful in getting grant renewals.

Q: Since you are a researcher and have worked with many researchers, what would you advise a beginning researcher to do to build their career?

Having a good mentor is the most important thing they can do. My mentor was Dan Levy, who led the Framingham Heart Study. One of the things he taught me was that it is important to learn a number of skills along the way.

It is also useful to have several mentors; one can help with career plans, and another with expanding research interests. And you develop more skills.

Scientists need to learn more than their own field, and that is why we developed the reproducibility training requirement. For instance, a biologist may not know anything about experimental design.

Q: What would you advise a graduate student to do to find a good mentor?

Word of mouth is the most helpful way. One of my potential mentors was too busy to meet with me, and so I asked around to find someone else.

Q: How would you advise mentors on how to be better mentors?

The most important thing is time. Time is the most important dimension. My mentor was wonderful to me because he was generous with his time. He would meet with me daily or every other day. He showed me tolerance also, and how to deal with difficult people. He made me practice my talks and rehearsed me. He would tell me to do it over. He has enormous generosity in terms of time. He also treated other people the same. He gave to others.

Q: What do you think about the research and writings of Dan Ariely and others who are conducting experiments about honesty versus dishonesty?

It tells us we can't dismiss dishonesty by thinking there are only a few bad apples. He demonstrates how we all might cheat. The important part is he has proposed ways to prevent it – like signing pledges.

Q: What are your thoughts on developing programs to enhance mentoring?

Ultimately, academic institutions are responsible for developing mentoring programs and training mentors. NIH has an interest as well; for example, the NIH Common Fund supports a mentoring consortium (the National Research Mentoring Network, https://nrmnet.net).

Q: How do you advise institutional leaders on their roles to promote integrity?

It is all in how you conduct yourself – it is like being a good parent. If you do wrong things, you send the wrong message.

If a chair or dean put their name on a paper that they did not contribute to, then they are sending the wrong message.

If you feel you have to turn in a colleague, you need to do it, even if worried about consequences.

Q: What do you think institutions could do to provide more protection for whistleblowers?

When I worked in the IRB world we used a hotline. An anonymous call that provides enough leads and details works can help.

NIH Peer Review Integrity

Patricia Valdez, PhD, and Sally Amero, PhD, National Institutes of Health

The integrity of the National Institutes of Health (NIH) peer review process relies on reviewers, applicants, and federal officials to uphold the core values of peer review, which include expert assessment, transparency, impartiality, fairness, confidentiality, research integrity, and efficiency.[1, 2]

If you've ever served on a peer review panel for the NIH, you may recall signing a confidentiality agreement in which you agreed to not discuss the contents of the review meeting with other individuals and to destroy all materials related to the review after the meeting. But what if a reviewer decides to share one of the applications with a postdoctoral fellow or a colleague down the hall? There are several possible consequences, depending on the nature of the breach, including: 1) the NIH may contact the reviewer's institution to notify them of the breach in confidentiality; 2) the reviewer may be removed from NIH council or review committees; or 3) the case may be referred to the NIH Office of Management Assessment (OMA), and possibly to the Department of Health and Human Services Office of the Inspector General (OIG).[3] Always remember, what happens in peer review stays in peer review.

Last year, the NIH published a notice outlining applicant responsibilities in maintaining the integrity of the NIH peer review process.[4] Applicants are not allowed to contact reviewers to request information about the review, to provide additional data for the application, or to otherwise attempt to influence the outcome of review. Applicants should only communicate through the NIH Scientific Review Officer (SRO) and they should not attempt to access unauthorized review materials. But what should a reviewer do if an applicant calls to discuss his application? In short, the reviewer should end the conversation and immediately report the applicant's behavior to the SRO. As with reviewer breaches, there are several possible consequences for inappropriate behavior by an applicant, including: (1) the application may be deferred or withdrawn from peer review, (2) NIH may contact the applicant's institution to notify them of the behavior, or (3) the case may be referred to the NIH OMA and possibly to the Department of Health and Human Services OIG.

In addition to maintaining the integrity of peer review, both reviewers and applicants must comply with PHS policies on research misconduct, defined as fabrication, falsification, and plagiarism. For example, if a reviewer lifts sentences, data, or ideas from an application and presents them as his own, the reviewer may be accused of plagiarism.[5] Likewise, if an applicant includes someone else's sentences, data, or ideas in their application without proper attribution, the applicant may be accused of plagiarism. Allegations of research misconduct in NIH peer review are referred to the Department of Health and Human Services Office of Research Integrity (ORI). Individuals found to have engaged in research misconduct may face administrative actions, but not limited to: 1) a requirement for certification of attribution or authenticity in all requests for support and reports to the PHS; 2) prohibition from participation in any advisory capacity to the PHS; or 3) debarment or suspension.

Federal officials also have a responsibility to safeguard the integrity of the peer review process. This includes ensuring that individuals with PHS administrative actions against them are not selected to serve on review committees.[6] SROs work to recruit reviewers with the appropriate expertise, and to make sure the meeting is run with integrity.

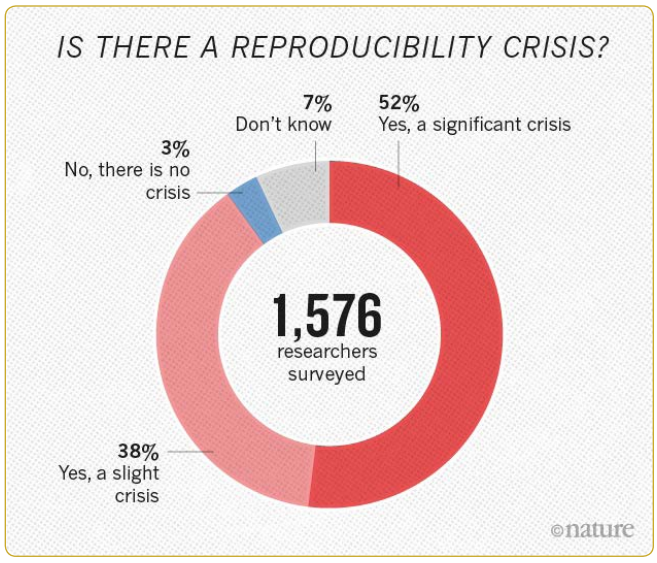
We can all work together to protect the integrity of the peer review process, and to meet the NIH goal to "exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."[7]

[1] http://grants.nih.gov/grants/PeerReview22713webv2.pdf
[2] http://grants.nih.gov/grants/peer/confidentiality_peer_review.htm
[3] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html
[4] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html
[5] http://ori.hhs.gov/ori-policy-plagiarism
[6] https://ori.hhs.gov/ORI_PHS_alert.html?d=update
[7] https://www.nih.gov/about-nih/what-we-do/mission-goals

Conversations about Reproducibility in Research Highlight Complexity and Progress

The need to reproduce research results; that is, to validate findings; is a critical but often overlooked element of the scientific method. When we read research results, do we too often assume they are defensible and authoritative just because they have been published in a peer review journal? Should the scientific community be more aggressive about reproducibility? It appears so. According to a survey of readers, two-thirds responded that reproducibility is a major problem (1). The problems with results that can't be reproduced include the risk that others will proceed with follow-on research that is based on a false lead or that someone will act on the results in a way that could have negative consequences.

But just agreeing on what constitutes reproducibility is a challenge. In a *Nature* editorial that accompanied the survey results, the authors note that "reproducibility can occur across different realms: empirical, computational, and statistical" (2, p. 437). They also note that scientific disciplines might disagree on what constitutes reproducibility. For example, data scientists might assume it means reaching the same conclusion using the same data. Laboratory scientists might assume it entails achieving the same results by using the same methods and materials. Even the degree of reproducibility needed is often a contentious issue. Some scientists might concede that reproducible findings can arise from "generally consistent results across slight variations in experimental set-up," according to Ferric Fang, a microbiologist at the University of Washington in Seattle, who spoke on the issue at a June 2016 meeting on the topic, convened by the National Library of Medicine (NLM), the Friends of the NLM, and Research!America (3). Others presume results are reproducible only if another scientist obtains the same results after replicating the exact experiment.



Rather than getting bogged down in finding a definition all can agree to, some have asked for clarifying language that pinpoints what is being reproduced; for example, methods, results, or inferences (3). In the end, each discipline might have to define for itself what constitutes reproducibility given the methods and analytical approaches unique to their field.

The *Nature* survey found that 70 percent of respondents had at some point failed to reproduce the results of others, and a surprising half failed to even reproduce their own results. Fewer than 20 percent of survey respondents reported ever being contacted by another researcher who was unable to reproduce their work. So, what explains these numbers? Respondents cited several barriers to improving reproducibility, including the added time and costs incurred by someone trying to reproduce either their own work or that of another researcher. In addition, the "incentives to publish positive replications are low and journals can be reluctant to publish negative findings" (1, p. 454). Some respondents to the *Nature* survey who were able to publish a failed replication reported that journals asked them to minimize comparisons with the original study.

Perhaps more troubling is the response by 60 percent that the research methods themselves likely contribute to low reproducibility. That is, selective reporting of results, low statistical power, weak experimental design, or use of highly unique reagents or techniques often result in poor reproducibility. Add to that the pressure to rapidly submit research findings to publications—the coin of the realm for academic scientists—and time is not allowed for replication of results. But that does not necessarily translate to research misconduct. Collins and Tabak noted that much of poor reproducibility is likely to "have simple and practical explanations: different animal strains, different lab environments or subtle changes in protocol." (4, p. 612) In 2016, NIH issued updates to application instructions and reviewed language intended to enhance reproducibility through rigor and transparency, which will apply to NIH-funded research (5).

The good news is that even in advance of the new NIH policy, the scientific community has recognized the problem and has been discussing it for the past few years, further raising awareness. One in three respondents to the *Nature* survey indicated that their laboratory has been active in efforts to improve reproducibility. Actions include encouraging that time be taken to repeat published work, ensuring there is a trail from the raw data to the final reports, improving design and statistical power, and relying on third parties to help review data to avoid "cherry picking" results.

For ORI, the issue is not necessarily that poor laboratory practices that contribute to irreproducibility also lead to misconduct; the issue is that irreproducibility reflects the need for more internal checks and balances among scientists. Checks and balances also will help reduce the opportunity for research misconduct.

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4. Francis S. Collins and Lawrence A. Tabak. "Policy: NIH plans to enhance reproducibility." *Nature* 505:612–613 (30 January 2014). doi:10.1038/505612a

5. NIH. Rigor and Reproducibility. http://grants.nih.gov/reproducibility/index.htm

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The Professionalism and Integrity Program (PI Program) What Have We Learned After Three Years?

James BuDois, DSc, PhD,
Washington School of Medicine

When we launched the Professionalism and Integrity in Research Program (PI Program) in 2013, we had many unanswered questions:[1]

- Who would get referred to the program?
- In one workshop, could we work effectively with researchers from different cultures, at different career stages, who do different kinds of research?
- Would participants open up to us? Would they speak plainly about why they were referred?
- What were the root causes of their difficulties?

At the same time, we knew that institutions often wrestle with what to do with researchers who get in trouble—researchers who are consistently persistently non-compliant or have lapses in research integrity. Traditional options are often extreme: terminating employment (severe) or offering a letter of reprimand while requiring a repeat of online training (mild). We also knew that physicians had access to remediation courses that demonstrate positive outcomes. (Two leaders of such programs—William Norcross and William Swiggart—joined our development team and were very generous in helping us to develop our workshop curriculum.) Finally, we knew that data suggested that traditional RCR education was unlikely to improve the behavior of those who got into trouble. In short, we knew there was both a need and precedent for this kind of training—even though no such training programs existed in the world of research.

About the PI Program Workshop

The PI Program is built around a three-day workshop. Participants travel to St. Louis. Workshops are led by two faculty members. All of our program instructors have doctoral degrees in clinical or experimental psychology, have served on institutional review boards, have done government-funded research, and underwent extensive training on the curriculum. Workshops are held with three to eight participants. We have now trained researchers from 24 different institutions.

Workshop sessions explore a variety of issues: core values in research; the hidden assumptions we make; self-serving bias; workplace and personal stress; management skills; and workplace obstacles to compliance and research integrity. On day two, participants share their stories: they explain why they were referred, explore why it happened, and troubleshoot the situation to identify ways of avoiding such problems in the future. These discussions last about 45 minutes per participants and many participants consider this to be the highlight of the program. It can be cathartic and lead to new insights. Participants are supportive of each other as stories are shared, even when they sometimes challenge each other.

On day three, participants write professional development plans. These are highly individualized plans that address the diverse factors they identified as presenting challenges to compliance or research integrity in their work. Plans include tasks such as: meeting with research team members regularly (usually weekly), obtaining further training on a specific issue (e.g., FDA requirements), creating a better system for data storage and sharing, conducting self-audits within a lab, or identifying a mentor.

Following the workshop, faculty conduct two, three, or even four follow follow-up calls with participants to coach them as they work through their professional development plans.

Participants additionally complete a battery of assessments before and after the workshop. Assessments examine their use of decision-making

[1]During the first year of the program, it was called the RePAIR Program—short for Restoring Professionalism and Integrity in Research Program. After a year, we changed the name to emphasize its positive nature.

strategies, levels of self-serving bias, knowledge of RCR rules, and work-related strengths. These data sometimes help us to identify specific needs of participants; they also indicate that the program is effective in achieving some of its key aims (such as reducing self-serving bias and increasing the use of good problem-solving skills).[2]

Our General Experience Running Workshops

After three years of running the PI Program, we are in a position to answer the basic questions we had as we launched.

Who gets referred and why? The researchers who get referred tend to be talented and productive. They are investigators that institutions wish to retain. The most common violations leading to referrals include: failure to provide adequate oversight, which led to other problems; informed consent violations; plagiarism; inappropriate recruitment of human subjects; and animal care violations. About three in four participants are male, and slightly more than half of participants were born outside of the United States.

Can One Workshop Meet Diverse Needs? Nearly all of our participants share some things in common: they do empirical research (as opposed to humanities scholarship), they have held some research funding (whether government or industry), and they are postdoctoral. Thus, they struggle with some similar things: having enough adequately trained staff, obtaining funding, and publishing while juggling other career responsibilities. Yet, with this much in common, we have found that it is actually an advantage to have researchers at different career stages, from different cultures, who do different kinds of research. This enables participants to adopt an outsider's perspective when providing feedback to others, and we have the opportunity to learn from very different experiences. Moreover, the approach we take requires each individual to examine how general questions pertain to their specific situation, culminating in an individualized professional development plan.

Do Participants Open Up to Us? As director of the program, I can say that this unknown kept me awake at night prior to our first session. And then our first participant—someone who really did not want to attend the program—shared his story with the group for nearly an hour. He shared ways in which he did not pay enough attention to compliance details and ways in which others in his department contributed to the problems. He was very open to input from the group regarding how to move forward positively, and the group was forthcoming with encouragement and suggestions. This set a tone for the entire first session, and subsequent sessions have followed a similar path. In the early years, we always did an intake interview with an official at the referring institution; we still prefer to do such interviews, but it is now optional and is done at the request of the participant or the institution in about 50% of cases. In general, when we do such interviews, we find that what we learn is confirmed during our workshop discussions; that is, participants are forthright about what they did. Of course, we hear different perspectives on the situation, but the basic facts presented by institutional officials and participants are generally consistent.

What are Some Root Causes of Violations?

In a recent article published in *Nature*, we explored root causes of the problems that led participants to be referred to our program.[1] Our PI Program faculty reviewed the situations of the 39 researchers we worked with over the past three years to examine what factors explained how the problems arose. We came to the conclusion that each of the following problems were at the root of 50% or more of the cases:

1. ***Lack of Attention.*** The researchers who attended our program were often very busy—balancing responsibilities as physicians, teachers, or administrators with doing research, seeking research funding, and ensuring compliance and integrity. Sometimes the participants were highly ambitious and simply took on too many projects. Those who got overextended were not always supported by diligent and

[2] We have analyzed data from our first three years. These data will be presented in a forthcoming publication.

well-trained staff, which meant that failures to provide oversight enabled serious problems to occur. Such problems include enrolling participants into studies using an outdated consent form, failing to follow anesthesia protocols in animal research, or publishing falsified data.

2. ***Uncertainty about the Rules.*** Sometimes our participants were inadequately familiar with compliance requirements or the rules for properly citing a source (e.g., they cited their sources but did not put excerpts in quotation marks). Here, too, there were often more ultimate causes. Uncertainty about rules often arose as researchers moved into new areas of research (e.g., conducting research with select agents for the first time, or conducting their first investigator-initiated clinical trial—their first trial without the compliance support provided by industry). In other cases, the regulations simply grew more complicated than when the participants first started their careers. Many animal care protocols are now more complex than they were 20 years ago and such protocols are often more complex in the United States than in other nations.

3. ***Not Prioritizing Compliance.*** This problem was sometimes itself a root cause of the first two problems. Without intentionally meaning to violate rules, our participants often did not view compliance as a basic component of doing good research and did not discuss compliance expectations with staff. Sometimes they failed to understand how severe the consequences of noncompliance would be for themselves, their human or animal subjects, their labs, or their institutions.

However, it was sometimes difficult to determine whether a lack of attention to compliance was due to priorities rather than participants' personalities or work-related strengths. In our *Nature* article, we discuss findings from the StrengthsFinder assessment that we administer to all program participants. StrengthsFinder provides test-takers with a list of their top 5 job-related strengths from a list of 39 possible strengths. Two talents were prominent in our group—learner and achiever—not surprising, given that these individuals have dedicated their lives to research and achieved doctoral degrees and faculty positions. However, conspicuously absent from 95% of our sample were strengths in discipline, focus, and communication—strengths that one would expect to support the detail-oriented work of ensuring compliance and data integrity. As we note in the article, we have no reason to believe that such a profile is unique to our PI Program participants.

What Can Institutions Do?

A knee-jerk reaction is to assume that one-size-fits-all educational requirements can address whatever deficits we find among researchers. However, supporting research compliance and research integrity may actually require very different kinds of resources. Here I suggest just four.

1. ***Provide Support for Compliance through Staffing.*** As noted above, researchers tend to be strong in learning and achievement, which enables them to develop new hypotheses, situate their studies within existing literature, and work the long hours to execute a study. however, they may need assistance with some of the more detail-oriented aspects of compliance. Institutions can support compliance by providing investigators with highly trained, detail-oriented staff to assist with matters of compliance and research integrity. Although current rules hold principal investigators (PIs) responsible for all aspects of a study, including its integrity and compliance, this does not necessarily mean it is responsible for an institution to leave such matters entirely to PIs.

2. ***Examine Researcher Workloads and Consider Right-Sizing Labs.*** As we saw, one reason why researchers get into trouble is being overextended and providing too little oversight. Department chairs or division directors may need to look at the overall workload of PIs whenever they receive new grant awards or contracts to consider their overall workload—not just to ensure compliance

with effort reporting (e.g., by encouraging the work week to increase in length), but to ensure that competing responsibilities will not interfere. In principle, the number of grant awards an investigator can hold responsibly, or publications an investigator can publish responsibly, is very large—if the investigator and the lab have adequate resources. Sometimes lapses should be addressed by down-sizing a lab; but sometimes they should be solved by growing a lab and its resources. Institutions may need to invest in labs—bridging support for staff members—in order to ensure that labs have the staffing they need to work in a responsible manner.

3. ***Listen and Educate as Needed; Provide Knowledge on Demand.*** In a recent study of 400 NIH-funded researchers, we found that hours of RCR education did not correlate with knowledge of RCR rules.[2] We cannot assume investigators know the rules just because they completed compliance training. People learn when knowledge is salient. Institutional administrative staff can help investigators by listening carefully whenever matters of research integrity and compliance are discussed, and educating as needed. Institutions can assist investigators by making knowledge readily available on demand. Websites should provide information that is up-to-date and easy to find when investigators have questions.

4. ***Consider Referral to the PI Program!*** The PI Program is not suitable for all cases of research lapses. The PI Program cannot provide individualized therapy. It it is not appropriate for individuals whose problems arise, say, from a substance use disorder. The PI Program also is not appropriate for a first-time lapse in compliance that might be easily remedied through basic education. However, we believe we have developed an excellent resource for investigators who are clearly struggling with compliance or research integrity—who need new skills in lab management, who need to improve their professional decision making, or who need to re-examine their priorities. More information on the PI Program is available at www.integrityprogram.org.

Unfortunately, all four of these recommendations include components that cost time and money, which raises serious questions about how institutions, the government, and society as a whole will fund research that is rigorous and valuable. However, each of the recommendations also speaks to the need for leadership at different levels—the levels of principal investigators, staff educators, department chairs, and research administrators. Resources will always be limited. The question is how to use these resources creatively to foster rigorous research that is conduct responsibly.

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Assessing the Effectiveness of RCR Education: Moving Forward by Looking Back

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Acknowledgements

We would like to thank Alison Antes, Jason Borenstein, Jeffrey Engler, Michael Kalichman, Brian Martinson, and Michael Verderame for their contributions to the present effort. The project described was supported by Grant Number ORIIR140010-01-00 from the National Institutes of Health and the Office of Research Integrity. The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of the Department of Health and Human Services or the Office of Research Integrity. Correspondence should be addressed to the Principal Investigator, Dr. Michael D. Mumford, Department of Psychology, The University of Oklahoma, Norman, Oklahoma, 73019 or mmumford@ou.edu.

Assessing the Effectiveness of RCR Education: Moving Forward by Looking Back

Research integrity is the cornerstone of scientific progress. When scientists are unable to trust one another's work, it impedes research efficiency and exploration. As Isaac Newton famously quipped, "If I have seen further than others, it is by standing upon the shoulders of giants." Research integrity also is fundamental to the reputation of science, influencing the public's attitudes towards scientific findings. Consider, for example, the present split in beliefs in the United States concerning the subject of climate change. In response to high-profile cases of scientific misconduct occurring throughout the last three decades of the 21st century, the United States government, through the Department of Health and Human Services, invested in identifying mechanisms for reducing research misconduct in the sciences (Kalichman, 2013). One key strategy employed in this regard is ethics education.

The National Institutes of Health (NIH), as well as the National Science Foundation (NSF), have issued mandates requiring that scientists receive training in Responsible Conduct of Research (RCR). However, decisions regarding how ethics training is delivered and what content is covered in training are at the discretion of ethics program directors and course instructors, giving rise to considerable variability in the core elements of instruction. More importantly, these courses have demonstrated wide variability in achieving their key objectives, such as improving knowledge of professional guidelines, ethical awareness, and decision-making capabilities. For example, a meta-analysis of 26 RCR courses conducted prior to 2007 found that, on average, courses resulted in only trivial benefits for trainees (Antes et al., 2009).

In the near decade of time that has lapsed since this last meta-analysis of RCR instruction effectiveness, the government has continued to invest in RCR program development by sponsoring research initiatives and providing resources to support course content development (e.g., Steneck, 2007). To assess the impact of these recent initiatives, NIH and ORI sponsored another meta-analytic effort (Grant #ORIIR140010-01-00), led by Michael D. Mumford and Shane Connelly at the University of Oklahoma, to investigate how RCR instruction has been carried out, how effective it is, and whether any improvements may be observed. Next, we summarize the methods and results of this effort.

Method

In order to identify studies to include in the meta-analysis, 26 major publication databases were searched, along with 14 journals relevant to RCR

and professional ethics. In all, we identified 66 studies reporting data from 106 ethics courses in the sciences, including the biomedical/health sciences, social sciences, and engineering. Studies included data from a total of 10,069 training participants. Each of these courses was coded by three trained judges to identify the areas of content covered (e.g., authorship and publication guidelines, Common Rule, whistleblowing) as well as the methods used to deliver training content (e.g., debates, lecture, cases). Finally, a Cohen's d statistic was calculated to assess the effectiveness of each course, where .20 or less indicates the training produced small or trivial benefits, .50 indicates moderate benefits from training, and .80 or above indicates substantial benefits to trainees.

Discussion

Overall, the results indicated RCR courses have, indeed, improved in recent years. The average Cohen's *d* of courses published from 2007 to 2015 was .56, which was noticeably greater than the effectiveness of courses published prior to 2007 (*d* = .36). These more recent courses also demonstrated improvements over the Cohen's d statistics reported in a prior meta-analysis of RCR courses (*d* = .37; Antes et al., 2009). In other words, sustained government investment in RCR education appears to have paid off. Although this is certainly good news, it is important to point out that while the average effectiveness of courses has improved, courses still differed considerably in their effectiveness, with some demonstrating substantial benefits to trainees, while others showed little, or in some cases, negative, effects. An explanation for these widely varying results may be found by examining the content and delivery methods used in RCR courses.

Instructional Content

The most effective programs with regard to instructional content covered topics such as personal integrity (*d* = .96), data integrity (*d* = .82), field differences in norms (*d* = .80), the Common Rule (*d* =.78), contemporary ethical issues (*d* = .67), whistleblowing (*d* = .64), authorship and publication practices (*d* = .60), and institutional compliance (d = .60). In contrast, programs including the following content areas demonstrated fewer benefits to trainees: power differentials (*d* = .18), peer review (*d* = .19), diversity (*d* = .19), civil maturity (*d* = .21), institutional values (*d* = .22), personal values (*d* = .22), and community issues (*d* = .23). By comparing more and less effective instructional content areas, it would appear that courses that overemphasized broad social issues at the expense of coverage of professional guidelines tended to provide little benefits to trainees.

Delivery Methods

Courses also differed with regard to how they delivered instructional content. We found the most effective courses employed the following methods and activities: note-taking (*d* = .85), debates (*d* = .63), analysis of current events (*d* = .60), review (*d* = .59), worksheets (*d* = .55), computer-based simulations (*d* = .52), and case-based instruction (*d* = .50). On the other hand, less effective courses emphasized mentoring (*d* = .19), service learning (*d* = .25), and book reviews (*d* = .29). In other words, courses employing activities that actively engaged trainees through interactions with key instructional content areas appeared more effective than those courses with activities focused on relationship building or passive learning methods.

In sum, RCR education appears to be improving. We used meta-analysis to summarize the results across many studies of ethics instruction courses and benchmark the progress of RCR education over time (Mumford, Steele, & Watts, 2015). The present effort also is noteworthy in that we identified a number of practical ways to improve RCR courses. Future courses may benefit, for example, from targeting instructional content to professional guidelines as they relate to the field in question and communicating this content through delivery activities that engage trainees in practicing the application of these guidelines.

Finally, we are in the process of expanding upon this research in three ways. First, we are investigating best practices in RCR education on a field-specific basis, such as identifying ideal content and delivery methods in biomedical ethics instruction (Mumford,

Watts, Medeiros, Mulhearn, Steele, & Connelly, 2016). Second, we are examining best practices in ethics course evaluation methods, because improvements in content and delivery methods are unlikely to result in measurably greater benefits to trainees if these benefits are measured poorly (Steele, Mulhearn, Medeiros, Watts, Connelly, & Mumford, 2016). Third, we are integrating the results of this meta-analytic effort into a predictive modeling tool. The purpose of the tool is to provide data-based recommendations to help RCR program directors and instructors improve their courses.

In conclusion, research misconduct threatens the very trust on which the scientific enterprise depends. Looking back, we are encouraged by the strides made in the improvement of more recent RCR education programs. Moving forward, we hope these research efforts spur further improvements along these lines as the scientific community strives to reclaim and build upon a reputation the public can trust.

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Pathway to "Building Research Integrity and Capacity" (BRIC) Training for Promotores

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Introduction

For more than 50 years, front-line health workers and advocates representing marginalized and health-disparate people have assisted public health practitioners and scientists to carry out valuable health service delivery and research.[1,2] These health advocates are often referred to as Community Health Workers (CHWs). While CHW is a common term used to describe these individuals, there are more than 100 different classifiers used across the globe, including, for example, Promotores de Salud, Patient Navigators, and Peer Leaders.[3] In this essay, we use the terms Promotor/a (singular masculine/feminine) or Promotores (plural). Promotores are increasingly involved with planning and implementing clinic and community-based research studies.[2,4] Training "research" Promotores is a focus of our research ethics training program that we call "Building Research Integrity and Capacity" or Project BRIC.[5] This essay describes the evolution of Project BRIC, including what we have learned from our recent research and the next steps to disseminate and encourage adoption of the BRIC curriculum.

The Evolution of BRIC

In 2000, shortly after NIH required training in human research protections for key personnel, our public health colleagues asked how they might train the Promotores assisting in community-based health research projects. Promotores are critical members of the research team, facilitating participant recruitment, conducting the informed consent process, implementing interventions, and collecting and transporting data from research participants.[6] Recognizing that training developed for academic researchers would be inappropriate for our local Latino/a Promotores, we requested and obtained support from NIH to develop a culturally-grounded, language-appropriate, and contextualized human research ethics training for Promotores. We called this educational initiative "Training in Research Ethics and Standards" (TRES).[7]

During the formative research phase of Project TRES, we learned that most Promotores were not familiar with the scientific method and its application to health research. This lack of foundational knowledge of research was critical to understanding and contextualizing our human research ethics training. With support from the ORI, we developed a foundational research literacy training, which we called "Basic Research Concepts." Both the TRES and Basic Research Concepts trainings were developed independently and hosted on two different websites. In 2013, ORI agreed to support merging of the training content, which we enhanced and re-branded as Project BRIC, and evaluating its effectiveness in improving Promotor research competencies. The BRIC curriculum consists of eight modules designed to facilitate Promotor learning about the research process and responsibilities when assisting with the design and implementation of research. The overarching objective of BRIC is to improve research literacy and promote the responsible conduct of health research in community settings. BRIC can be administered as a self-paced learning format or in a group setting delivered by a trained facilitator.

BRIC Research Questions and Methods

A mixed-methods approach was used to answer the following research questions:

(1) What competencies do Promotores need to carry out their research duties?

(2) How should these competencies be assessed?

(3) Does BRIC training improve research competencies as measured by the BRIC Inventory

when compared to a control condition (e.g., mental health training)?

During Phase 1, we conducted formative research to answer questions 1 and 2 and concluded that phase with the development of a BRIC Assessment Inventory aligned with learning objectives across each of the eight BRIC modules. Phase 2 involved conducting a randomized controlled trial (RCT) of BRIC with Promotores using the BRIC Assessment Inventory to evaluate outcomes.

Formative Research – Questions 1 and 2

Principal Investigators (PIs) and Project Managers (PMs) who supervise CHWs (i.e., Patient Navigators, Promotores, Peer Leaders) were asked to participate. Participants completed a survey to clarify how Promotores/CHWs were involved in their respective research studies, what training was provided, and priorities for skills and knowledge needed to perform research-related tasks. Of the 36 PI/PMs invited to participate, 19 attended one of four focus group sessions to inform development of an instrument to assess research competencies. In addition, we conducted one focus group with nine Latino participants who self-identified as Promotores to better understand their role as research facilitators and involvement in health research and health service delivery tasks.

PI/PM participants confirmed a role for Promotores in the implementation of research, but only half reported their involvement in the planning and reporting phases of research. The majority placed priority on Promotores being able to think critically on the job and apply ethical principles in their practices and placed less importance on knowing about the ethical review process or historical facts leading to human research protections. Focus group priorities for research ethics training content aligned with the BRIC modules, and as such, no substantive changes were made to the blended curriculum.[8]

RCT– Question 3

A two-condition randomized control trial (RCT) was designed to test the effectiveness of the Spanish-language BRIC curriculum in improving research knowledge among Promotores. All participants completed a screening questionnaire and the BRIC Inventory prior to and immediately following the intervention. The control group (n=20) received a psycho-education depression intervention called, "¿Es Difícil Ser Mujer?" (Is it Difficult Being a

Figure 1. BRIC Self-Assessment Examples

I CAN:

1. explain why it is important that information collected from a participant is accurately documented.
2. explain key differences between research studies and service programs.
3. explain why a research participant should be informed about potential study risks.

I KNOW:

1. why it is important to invite people to participate in the study who are similar to those who may benefit from the study results
2. why a specific strategy for collecting and analyzing information is used to answer a research question
3. my role in reducing the risk of harm to study participants

Figure 2. BRIC Critical Thinking Examples

1. How can you protect the confidentiality of research materials?
2. Explain how research may benefit the participant and the community represented.
3. Describe a strategy to improve the informed consent process.

Woman?), nine modified to be gender neutral, and the intervention group (n=24) received the BRIC curriculum. Both eight-hour trainings were delivered in Spanish at local community schools and clinic locations convenient to participants. All participants assigned to the control group were given the option to attend the BRIC training after completing a post-test.

To assess research competencies, participants recommended a self-assessment, short problem-based scenarios depicting realistic challenges faced in the field, and role-play to practice skills (i.e., conducting the consent process). To reduce the burden to supervisors who may administer the assessment, multiple-choice responses were preferred to an open-ended answer format.[10] In response to participant recommendations, the BRIC team created assessment items that included a self-assessment of competencies as well as problem-based prompts with open-ended and multiple-choice response options that aligned with BRIC learning objectives. See Figure 1 for examples of assessment questions from the BRIC Assessment Inventory.

BRIC Curriculum Description

The BRIC curriculum was adapted for presentation in a group setting using slides combined with active learning techniques that engaged the participants in the learning process. The modules include an introduction to basic research concepts (i.e., distinctions between health service project and health research, research design, data management), ethical principles (i.e., respect, beneficence, justice), and responsible practices contextualized to clinic- and community-based health research.[5] The eight modules were delivered in Spanish to monolingual and bilingual participants. The content was delivered verbatim from the BRIC manual in conjunction with slides that were used to provide visualization of the concepts (see Figure 3).

All participants completed a recruitment survey prior to being randomized, and the BRIC Assessment Inventory before and after completing the training.

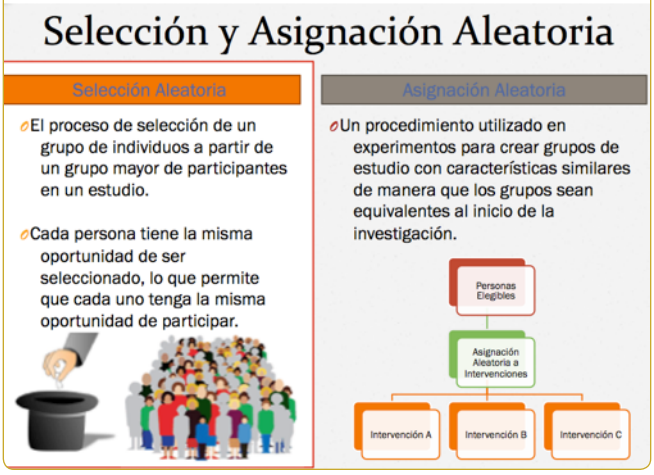
Participant Response to BRIC

The Promotores' response to the BRIC training was very positive. One participant commented (translated from Spanish to English), "Now I know what it means to be a Promotora!" with another asking, "Why have we not received this training before?" As reported previously, if a Promotor is not aware that the work they are doing is part of a research study, they may not know that making changes to the way they deliver the intervention can affect the study results.[6,7] One Promotora stated, "It's important that those who direct the projects are more open... They should explain to us what the objective of the study is, because we have to do the work, but we don't know what limitations we have or how we could hurt the study."[7] Responding to the BRIC Assessment Inventory was difficult for many of our participants, primarily due to the number of questions. We are presently analyzing response patterns to identify optimal questions to reduce the total number of assessment questions.

BRIC - Moving Forward

The positive impact of BRIC on Promotor learning, combined with the increasing opportunities for Promotores to be involved in health research, has prompted our team to consider the next steps to advance the dissemination and adoption of the BRIC curriculum. By educating Promotores about the importance of protocol adherence and their responsibilities as members of the research team, we contend that threats to data fidelity may decrease and the scientific integrity of public health research will improve. That being said, we know of no research documenting

Figure 3. Depiction of Random Assignment and Random Selection.



incidents of protocol breeches among Promotores or other CHWs, and we have not yet studied whether our BRIC intervention increases protocol adherence or reduces other threats to data fidelity. To explore these questions, we need to better understand the ecosystem in which CHWs operate. Once we characterize studies that engage lay research staff, we can examine current training practices and the extent to which supervisors (e.g., principal investigators, project coordinators) are: (1) aware of the potential threats to data fidelity that might be mitigated by adopting the BRIC training; and (2) able to adopt BRIC for research teams that include Promotores in the planning, implementation, and reporting of research. While some questions are unanswered, a case can be made that a culturally-grounded BRIC training will advance research integrity by providing Promotores and other CHWs with the skills and knowledge needed to conduct ethical and responsible research. To learn more about Project BRIC, visit: http://bric.ucsd.edu.

Acknowledgements

The work referenced in this essay was supported by NIH (Nebeker, Principal Investigator, 2002-08 (T15, JL072440, NHLBI)) and ORI (Nebeker, Principal Investigator 2004–2005 (HHSP233200400813P) and 2013–2015 (ORIIR130005-01-00)). The content of this paper is solely the responsibility of the authors and does not necessarily represent the official views of the Department of Health and Human Services, NIH, or the ORI. The authors also acknowledge the significant contributions of our community partners including the community leaders affiliated with the San Diego County Promotores Coalition, academic colleagues, and local Promotores. BRIC investigators also acknowledge the generous contributions of our research assistants and interns including, (in alphabetical order): Osvaldo Arambulo, Elizabeth Booen, Mayra Cano, Rebeca Espinoza Giacinto, Andrea Gonzalez,Tiffany Lagare, Araceli López-Arenas, Jasmine Martinez, Blanca Azucena Pacheco, Alexandra Soto, and Daniela Vital.

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ORI Extramural Research Program Awards Five Conference and Five Research Projects

ORI awarded ten grant applications through Research on Research Integrity program. Five Conference grants and three new Phase I Research grants were awarded. Two successful Phase I Research projects from fiscal year 2015 were approved for Phase II funding.

Research Grants: The purpose of the Phase I research grants is to foster innovative approaches to empirical research on societal, organizational, group, and individual factors that affect, both positively and negatively, integrity in research. These grants are awarded in two phases:

- **Phase I**: The objective for Phase I is to establish project merit and feasibility and to generate preliminary data prior to seeking further support for Phase II.
- **Phase II**: Phase II constitutes a separate competition limited to successful Phase I awardees. The objective for Phase II is to build upon results achieved in Phase I. Funding is based on success demonstrated in Phase I, the merit and feasibility of the Phase II proposal, and the availability of funds.

Conference Grants: The conference grants aim to provide an opportunity for the research community to develop multi-disciplinary networks, build on existing evidence-based research, and stimulate innovative approaches to preventing research misconduct and promoting research integrity. ORI is especially interested in supporting conferences that lead to extramural grant applications on research on research integrity and peer-reviewed publications.

Research Conferences on Research Integrity

Promoting Research Integrity in Collaboration with the Asia Pacific Region

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Abstract

The proposed conference, co-hosted by the University of Hong Kong and the University of California, San Diego, will be the first meeting of the newly formed Asian and Pacific Rim Research Integrity (APRI) network to be convened in Asia. Acutely, this meeting is an opportunity to foster research integrity through multi-national awareness, understanding and opportunities for collaboration. For the long-term, this is an essential next step in the creation of a sustainable, robust international partnership that will continue to promote research integrity in the region. For these purposes, the meeting is defined by four objectives:

(1) Articulate differences as well as areas of common ground.

(2) Identify best or recommended practices.

(3) Identify opportunities for research or collaboration.

(4) Set an APRI network agenda for coming years.

The key outcome anticipated is to advance the conversation surrounding research integrity among

Asian and Pacific Rim nations. This outcome will be evidenced directly through five products: a) meeting participation b) satisfaction, c) a white paper, d) publication and dissemination, and e) articulating next steps for the APRI network.

Growing Research Integrity Together (GRIT) Conference

Samuel Gannon, Ed.D.

The Vanderbilt University

Abstract

The goal of this proposal is to build on the successful platform of Vanderbilt University's Growing Research Integrity Together (GRIT) Conferences to define practical, cross-disciplinary, and multi-level practices to foster institutional integrity in research through a nine-month Delphi consensus process, culminating in a three-day multidisciplinary conference on research administration in team science. The focus of this conference will be on research administrators as a locus of responsibility for institutional integrity in the increasingly complex academic research environment. We will use grant funds to support travel and related costs for 10 multi-disciplinary content experts to serve as Delphi-process panelists and attend the June 2017 GRIT Conference, where they will present the Panel's conclusions and recommendations and engage with the 100+ conference participants in interactive sessions to refine their identified best practices. For the GRIT Conference proposed here, we have planned 3 days of didactic and active learning sessions on key issues in research integrity, exploring contemporary standards of responsible conduct and common causes of research misconduct, including individual, situational, organizational/institutional, structural, and cultural factors. Each afternoon we will share the conclusions of the Delphi-process deliberations on institutional obstacles and facilitating factors in research integrity, with formal presentations from the Panel's subject matter experts. Each formal presentation will be followed by breakout group discussions and structured feedback using a community engagement and deliberation process to examine, critique, and refine the Delphi panel's conclusions and recommendations and propose means of their implementation.

Leveraging the Research Integrity Symposium to Promote Metacognitive Ethics in Research Education and Training

Ross A. Hickey, JD.

University of Maine System

Abstract

The Research on Research Integrity (RORI) workshop is an innovative concept for assembling researchers, administrators, review board members, and other regulatory professionals as a forum and as a replicable laboratory for studying how ethical decision-making is impacted by social and cognitive processes. The day-long RORI pre-conference and its broader associated research network will be integrated with and will leverage the energy and logistics already in place within the highly successful Maine Research Integrity Symposium. The aim is to form a network of experts working to shape a new paradigm in ethics research and training centered around metacognitive principles underlying ethical reasoning. Participants will first directly experience opportunities for decision-making designed to evoke psychological mechanisms known to impact research behavior. Results will then be presented as part of a RIO roundtable for full discussion and analysis and integrated into a plan for dissemination and broader development of research and implementation within our network of committed regulatory professionals.

Inter-American Encounter on Scientific Honesty

Sergio Litewka, M.D.

University of Miami

Abstract

The overarching goal of this project is to foster a culture of research integrity in academic institutions in Mexico through the work of an Inter-American Encounter on Scientific Integrity. This conference will bring together upper-level administrators and research educators from national universities with representatives from funders, scientific journals, and the country's growing bioethics community to (1) characterize the types and perceived prevalence of misconduct in Mexico's academic research environment; (2) develop a framework for institutional policies and procedures to prevent and respond to misconduct and questionable practices in research, particularly in international collaboration; and (3) build a multi-disciplinary network of academic researchers, educators, and administrators actively engaged in new approaches to promoting integrity and preventing misconduct in universities across Mexico. Working with Spanish-speaking research integrity educators from the United States, participants in a pre-conference workshop will develop a provisional definition and typology of misconduct relevant to Mexican universities, estimate the scope and perceived frequency of scientific dishonesty in the country's academic research environment, and set priorities for policy-oriented topics to be addressed in the larger conference. Members of this working group will serve as speakers and discussion group facilitators in a larger, open registration conference that will (1) address potential policies and procedures on responsible conduct through which academic institutions can support the integrity of their faculty's and students' research, particularly in international collaboration; (2) examine the specific challenges to research integrity that arise in the Mexican context and define the obstacles to effective implementation of academic policy in the national context; and (3) propose ways to overcome those obstacles in their own institutions and across the country. Themes to be addressed include: (1) defining, preventing, and responding to research misconduct; (2) standards of authorship and responsible publication practices; (3) conflicts of interest and their management; (4) data collection, management, ownership, and sharing; (5) collaborative research and divergent international policies; and (6) developing a curriculum on research integrity and responsible conduct of research. The conference will enhance academic leaders' and research educators' awareness of the positive role of policy in promoting research integrity and their readiness to develop a policy framework in their home institutions.

Supporting Responsible Research Organizations: A Framework for Engaged Research Managers and Administrators

Dade, Aurali, Ph.D.

George Mason University

Abstract

Research scientists cannot effectively deal with the responsible conduct of research in a vacuum. They are in need of solid support from their institutional administrative communities. That support cannot be provided without thoughtful consideration of the issues, practical knowledge of the prevailing rules and regulations, and a vested interest in championing the public trust and safeguarding research subjects' (human and animal) welfare. Research administrators have a front row seat to view how research is conducted and administered in various settings: universities, hospitals, academic medical centers, nonprofit foundations, research institutes, and industry. They are involved at all stages of the research process – from the development and pre-award phase though to project closure. As such they can be independent observers to the research process as research occurs. Yet, often they do not realize the integral role they play in maintaining and supporting an institutional environment that supports research integrity and the Responsible Conduct of Research (RCR).

This joint George Mason University and Society of Research Administrators International (SRAI) project will seek to provide a two-day research integrity management intensive workshop (RIMI) that provides research integrity leadership training for administrative leaders and results in developing a guidance document and other resources for research administrators. Course curriculum will deal with RCR core content and explore the complex roles of grants administrators, research subject committee administrators, and research integrity and compliance officers and how they interconnect to support and protect the research enterprise. It will use a mix of teaching and case study instructional methods to highlight to research administrators how they may play a more active role in monitoring RCR issues through the research process.

Phase I Research on Research Integrity

Misconduct Framing and Questionable Research Practices

Bruton, Samuel, Ph.D.
Sacco, Donald, Ph.D.

The University of Southern Mississippi

Abstract

For the past three decades, federal and institutional efforts to promote research integrity have focused largely on research misconduct, standardly defined as fabrication, falsification, and plagiarism (or "FF&P"). These efforts have included the development of educational materials for promoting research integrity as well as the detection and prosecution of those who commit research misconduct. However, there is growing evidence and discussion in science that other ethically questionable research practices – "QRPs" – also may be prevalent, significant, and a malign influence on the overall quality of research. Increasingly, signs suggest that QRPs ultimately may be as damaging to scientific progress as research misconduct, narrowly understood (Ioannidis, 2005). In response, The University of Southern Mississippi is proposing an innovative research project to investigate a potential psychological mechanism associated with QRP endorsement and subsequently to test the efficacy and effectiveness of a promising behavioral intervention designed to stop individuals from engaging in research misconduct, broadly construed.

We intend to explore the possible impact of a well-established psychological process (Tverksky & Kahneman, 1981) in a context in which it has been previously explored or discussed. Specifically, we will test how framing research misconduct as FF&P may influence attitudes and behavior towards non-misconduct QRPs. We will then test a novel means of improving researchers' commitment to ethically sound research practices. Goals: We propose to conduct two studies: (1) to determine the impact of a possible framing effect on researchers' favorable attitudes towards QRPs, and (2) to test a behavioral intervention designed to favorably influence this effect. Study 1 will examine whether conceptualizing research misconduct in the strict sense of FF&P affects attitudes towards QRPs, i.e., deviations from ethically sound research practices other than FF&P that affect the quality of scientific research. Study 2 will test a behavioral intervention designed to promote scientific integrity by means of this framing effect. Objectives: Study 1 participants (academic researchers) will be assigned either to a misconduct framing condition or a control condition. The QRP assessments of both groups will be compared to determine whether misconduct framing leads to endorsement of QRPs. Study 2 participants (academic researchers) will be assigned to a misconduct framing, control, or QRP mitigation condition. Participants' QRP assessments will be analyzed to replicate Study 1 findings and to determine which intervention most reduces QRP endorsement. Outcomes: In Study 1, we predict that participants in the misconduct framing condition will demonstrate more favorable attitudes towards QRPs than those in the control condition. In Study 2, we predict that the results of Study 1 will replicate and that participants in the QRP mitigation condition will demonstrate the least favorable attitudes towards QRPs. Products: Data from these two studies will be used to generate at least two high quality conference presentations (e.g., Association for Psychological Science, Association of Practical

and Professional Ethics) and at least two publications in scientific journals of specific (e.g., *Science and Engineering Ethics, Accountability in Research*) and general interest (e.g., *Psychological Science*). Results of both studies also will be disseminated electronically by means of the national IRB Forum and APA listservs. Results also will be used to design a Phase II project expected to expand our findings and their impact by developing additional intervention strategies to reduce researchers' perceptions of QRPs as ethically defensible and to increase their perceptions of these practices as detrimental to the advancement of science.

Reproducible image processing by improved tool development

Paul A. Thompson, PhD

Sanford Research

Abstract

Reproducibility in science is a current concern for many researchers. Reproducibility refers to the requirement that results of published studies are able to be redone from the source data. Most types of image processing are not done reproducibly, as most image processing is done interactively in programs like Photoshop, ImageJ, and GIMP (GNU Image Manipulation Program). Due to the interactive processing to produce final images from source, published images are not easily or exactly reproducible, and additionally, researchers have a temptation to engage in inappropriate and sometimes fraudulent image processing.

To make image processing reproducible, a scripted approach to image processing is necessary. Image processing is done interactively, but a "journaling" process (in which the interactive process both processes the images and generates code which can perform the same task) can be used to make the interactive processing transparent, reproducible, and auditable. Allowing scientists to process images interactively while also creating a transparent record will improve reproducibility and decrease fraud.

This proposal presents a plan to incorporate a journaling function into open-source image processing tools such as GIMP and R. GIMP is an open-source tool which feature well-defined approaches to revising the tool and making contributions. In the GIMP system, a journaling function will be implemented in one of two ways. Either the main code system will be modified (which is allowed as GIMP is open-source), or an add-in will be created that performs the journaling function. R is a system for general information processing and includes tools for GUI creation and image processing. In the R approach, the Shine GUI (graphical user interface) builder will be used to create a GUI, which can both modify images (using ImageMagick code) interactively and save the ImageMagick code as the modification is performed. Tools will be examined and produced, a code system for scripted image processing will be selected, and the approach will be tested on images prepared for publication as scientific images.

Image editors with a journaling function will be a strong deterrent to image fraud. By processing images with a tool that shows a clear track of all processes, scientists processing images will use appropriate methods, and fraud will be deterred. Transparency is the most effective deterrence to fraud. In addition, as fully disclosed modifications of images will be done, future changes in image processing can be incorporated.

The Value Of Statistical Tools to Detect Data Fabrication

Chris HJ Hartgerink

Stichting Katholieke Universiteit Brabant

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 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. In Project 2, we interview these researchers to investigate 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.

Phase II Research on Research Integrity

Bioethical Issues in Biostatistical Consulting (BIBC): A Phase II Study

Min Qi Wang, Ph.D..

University of Maryland, College Park

Abstract

Following the successful implementation of the phase I study, the overall purpose of this phase II study, in collaboration with the American Statistical Association (ASA), is to conduct a full-fledged study to investigate the frequency and relative severity of a broad array of bioethical violations requests that are presented to U.S. biostatisticians by investigators seeking biostatistical consults. A 35-item Bioethical Issues in Biostatistical Consulting Questionnaire (BIBC Q), developed, construct validated and pretested within an NIH/NIDR-funded Oral Health Disparities Center (U54 DE14257-08), along with a short demographic data form, will be administered to a random sample of U.S. biostatisticians. There are four aims to be achieved. Aim 1: to establish the prevalence of 35 bioethical violation requests related to data analysis practices as broached to biostatisticians by investigators during biostatistical consultations. Aim 2: to determine the relative severity level, as deemed by biostatisticians, of each of those 35 “biostatistical consult” bioethical violation requests. Aim 3: to investigate the association of the response patterns to the 35 bioethical violation requests from investigators by (a) work experience, i.e., age and career length as a biostatistician; (b) gender; (c) race (White, Asian, Black/Hispanic, and Other race); (d) type of credentials/degrees; (e) broad employer type; and (f) field of

application (e.g., public health, health care, medical, pharmaceutical, etc.). Aim 4: to disseminate the findings including, but not limited to, the summary reports to the American Statistical Association (ASA), educational and training documents to ASA members via ASA web, and the ASA online user forum. The dissemination also will include national conference presentations and peer-reviewed publications. To achieve these goals, 400 ASA members representing statisticians working for the academia, government, and industry will be surveyed. The data will be analyzed and findings will be presented at national conferences. The educational and training materials will be shared with ASA.

Perceptions of Scientific Misconduct in the Natural and Social Sciences

Kristy Holtfreter, Ph.D.

Arizona State University

Abstract

Goals: This study assesses perceptions of various forms of scientific misconduct (e.g., data fabrication, falsifying findings, and plagiarism) from a representative sample of tenured and tenure-track university faculty in the United States. Specifically, this study examines researchers' perceptions of the prevalence, seriousness, causes, and prevention of scientific misconduct. Objectives: This phase (Phase 2) entails the continuation of data collection; mail survey data will be collected to compliment the online survey data. The sample consists of researchers employed at the top 100 research universities in the United States from three broad scientific fields—natural, social, and applied sciences. The analyses also will use high-order confirmatory factor models to develop a multi-dimensional scientific misconduct scale with strong construct validity. The analyses also will assess what factors are thought to promote scientific misconduct in a multivariate regression context. This portion of the study will make use of variables drawn from a number of criminological theories that have been empirically shown to explain unethical and fraudulent behavior. Empirical attention also will be directed toward the utility of potential prevention efforts. Outcomes: The study will produce an empirically-validated scale that may be used by future investigators. Importantly, two dimensions of the scale—resource mismanagement and disobeying institutional authority—reflect forms of misconduct that have yet to be empirically investigated. Finally, the results will be weighted to represent the population of interest, thereby reflecting the perceived prevalence and seriousness of scientific misconduct in the eyes of researchers. Products: In addition to reports required by ORI, the data obtained for this project will be used to produce several high-quality conference papers and multiple peer-reviewed publications in scientific journals of general interest. The results will be disseminated to the general public via the media and shared electronically.

Japan Agency for Medical Research and Development Invites ORI Division Directors to Tokyo for International Conference on Research Integrity

Japan is forging new paths in research integrity at the highest levels of government, institutions, and professional societies. After visiting the Office of Research Integrity (ORI) in 2015 and attending the Asia Pacific Research Integrity network meeting co-sponsored by ORI and the University of California San Diego in February 2016, the Japan Agency for Medical Research and Development (AMED) invited ORI Division Directors Dr. Susan Garfinkel and Ms. Zoë Hammatt, along with Senior Associate Vice President for Research and Research Integrity Officer at University of Virginia, Dr. David Hudson, to Tokyo for the "International Conference on Research Integrity: Learn from ORI" in June. The theme of the conference was prevention and investigation of research misconduct in biomedical research. Other speakers included Dr. Makoto Suematsu, President of AMED; Dr. Iekuni Ichikawa, Executive Director of the Association for the Promotion of Research Integrity; and Dr. Soichi Kojima, Unit Leader of the Micro-signaling Regulation Technology Unit at RIKEN Institute. The conference was held at the Tokyo International Forum and drew more than 200 participants, including leaders from the Japan Society for the Promotion of Science; Japan Science and Technology Agency; Ministry of Economy, Trade, and Industry; Ministry of Health, Labour, and Welfare; Ministry of Education, Culture, Sports, Science, and Technology; and major Japanese universities and research institutions. Dr. Naoko Akimoto of AMED coordinated Drs. Garfinkel and Hudson and Ms. Hammatt's visits to the Tokyo Institute of Technology, University of Tokyo, and other critical meetings with Japanese ministries to encourage collaboration on the promotion of research integrity in Japan and around the world. Dr. Hudson noted, "this gave us a wonderful opportunity to see that AMED is spearheading efforts in Japan to weave research integrity into the fabric of the stellar research enterprise that continues to flourish in Japan. Our collegial interactions with experts in the governmental ministries, professional societies, and research institutions helped elucidate the fact that Japan is taking research integrity to new levels. Those of us in the U.S. and abroad can learn a lot from their innovative approaches." Dr. Hiromichi Suzuki, Managing Director of the Department of Research Integrity and Legal Affairs, thanked ORI for its leadership and expressed tremendous gratitude for the contributions of ORI division directors and Dr. Hudson. Dr. Suzuki emphasized that the practical experience shared by ORI and the University of Virginia was highly beneficial for all attendees. AMED seeks to further strengthen collaboration with ORI and other U.S. institutions in the spirit of the longstanding friendship and cooperation between the two nations. To learn more about AMED, please visit the English website: http://www.amed.go.jp/en/

(Left) AMED leadership and senior institutional officials welcome the ORI and University of Virginia delegation.

Cooperation and Liaison between Universities and Editors over Suspected Research Misconduct: Have We Got a CLUE?

Elizabeth Wager

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Just as a research discovery may be considered not to exist until it is "reviewed and in print,"[1] similarly, the main forms of research misconduct only start to pose a threat when they are published. Therefore, journal editors are often the first people to suspect misconduct, which can happen before or after publication. For example, plagiarism or image manipulation may be spotted by peer reviewers or readers, or may be picked up by journal screening systems. However, although they may be among the first to be alerted to possible misconduct, and have a clear duty to protect their readers from false or misleading publications, journals are not equipped to investigate misconduct; therefore, cooperation between journals and research institutions is essential in such cases.

The Committee On Publication Ethics (COPE) provides guidance for journal editors about how to handle cases of possible misconduct. This advice is summarized in a series of flowcharts.[2] In most cases, COPE recommends that editors first raise concerns with the authors; but if they do not reply or their explanations are unsatisfactory, COPE advises editors to contact the authors' institution and request an investigation. Sadly, institutions do not always respond appropriately.[3] If an institution does not respond or refuses to investigate, the journal is put into a difficult position, especially when it has concerns about published work.

It is impossible to know how often problems arise, and rates probably vary between countries, but I have documented 12 cases that were brought to COPE's attention and have heard, anecdotally, of others.[3] For example, an editor I know carefully documented and raised a complex case with an institution that involved a multi-author, multi-center clinical trial publication. Two days later, the main university called the editor to say they had looked into her concerns and concluded there was nothing to worry about. The editor protested that it simply would not have been possible to contact the necessary people and review the evidence in such a short time, but the university curtly informed her that they had no intention of investigating further.

CLUE workshop participants at EMBO in Heidelberg, Germany.

While COPE provides a forum in which editors can discuss troubling cases, there is also clear evidence that journals do not always respond appropriately when alerted to fraudulent papers by institutions. One clear example of this was the case of Eric Poehlman, who was not only found guilty by ORI of fabricating data, but was also jailed for his fraudulent activities.[4] ORI contacted the 10 journals that had published the fraudulent work in 2005, but by 2015 only six of the journals had issued a retraction to alert readers. More recently, I looked at the case of anesthesiologist, Joachim Boldt, who had been shown by the German authorities to have published 88 articles describing research for which

ethical (IRB) approval had not been given (and some of which was later suspected to have been fabricated).[5] In this case, we found that only 5 of the affected articles (6%) were retracted properly, according to the COPE guidelines and in 9 cases (10%), the article had not been retracted at all.

Faced with this clear evidence that journals and institutions do not always cooperate optimally over cases of suspected or proven research misconduct, COPE has produced guidance on this topic.[6] The guidance is aimed at both journals and institutions and was drawn up after extensive consultation. However, we appreciate that this process may not be straightforward, so we want to explore the specific tensions and reasons why journals and institutions sometimes do not (or perhaps cannot) share information as fully as might be wished.

One question we hope to explore is how much evidence journals should gather before they contact an institution. Related to this is the question of whether editors should always contact authors to discuss their concerns before they contact their institution. The COPE flowcharts suggest this is usually appropriate, since it gives authors a chance to explain themselves, provide their side of the story, or offer an explanation. Sorting out an honest error in this way avoids wasting an institution's time if the suspicions or allegations of misconduct are unfounded; however, if journals raise concerns with researchers, this may also give them a chance to destroy evidence and impede or prevent a proper institutional investigation.

Another problem is what journals should do if published work is being investigated by the authors' institution(s) but the investigation will take a long time. This is of particular concern for clinical medicine journals, since doctors may base decisions on published research, and therefore, journals have considerable responsibility to avoid misleading their readers. In such cases, COPE recommends that journals consider issuing an Expression of Concern. However, this may be viewed as prejudicial to the researchers, who, even if cleared of misconduct, may find it difficult to salvage their reputations.

The questions surrounding journal and institution liaison over misconduct cases have been discussed at the World Conferences on Research Integrity (in Montreal in 2013 and Rio de Janeiro in 2015). Recently, a meeting of experts; including Zoë Hammatt from ORI, and participants from COPE and from journals and universities from around the world, including South Africa, Australia, the United Kingdom, and the Netherlands; was convened in Heidelberg, Germany, held at the European Molecular Biology Organization. The meeting (entitled Cooperation and Liaison between Universities and Editors, or CLUE) worked on developing further guidance which we hope to put out for consultation and discuss at the next World Conference on Research Integrity in Amsterdam in 2017. Please do get in touch if you would like further information or to be kept informed of our progress.

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Thoughts on Shaping and Reinforcing Honest Behavior

Sandra Titus, PhD

We read about the level of tax fraud, lies on insurance issues, conflict of interests, and research misconduct that seem unacceptably high. We know that many people in our culture are not always honest. According to the experiments by Dan Ariely, as discussed in his TED talk on "predictable irrationality," all people cheat a little bit of the time.

Even more alarming is that research by Welsh et al has shown small infractions may lead people to commit larger ones over time (http://www.ncbi.nlm.nih.gov/pubmed/24865577). This team believes slipping down the path of dishonesty happens because the person rationalizes and justifies each small infraction, and hence loses the ability to self-modulate their own behavior. I urge you to read this research and see whether you are convinced about the relationship.

Are there ways to interrupt the temptation to cheat?

Social behavioral economists have started to look at interventions to reduce cheating (Shu et al). First they found participants were less likely to lie about earnings when they were asked to sign a form or document at the top of the form and before completing it. They ran several different experiments in which a signature at the top led to the same finding. Their testing included a real-life setting in which consumers were asked to report their car's mileage for the past year, which was then compared to the U.S. Department of Transportation Office of Highway Policy information average driver's annual mileage of 12,500 miles. Those who under-reported their mileage, presumably to keep their insurance low, to be 12,500 annual miles were more likely to be the same individuals whose signature space happened to be at the bottom of the form.

The researchers then pondered why the placement of the signature mattered in terms of honesty. They conducted an additional component in their experimental design in which subjects were asked after they completed the form to fill in some incomplete spaces to complete a word. For instance: __ral, et__c__ (the full word might be moral, ethical). Subjects who signed the form at the top, who had been established in prior research as less likely to cheat, also were more likely to fill in the blanks with ethical word choices. The researchers' conjecture that signing first reduced the lying and the person acted more ethically, as reflected in their ethics-related word choices.

The authors conclude, "The power of our intervention is precisely due to the freedom of individuals. It does not require the passage of new legislation, and it can profoundly influence behaviors of ethical and economic significance." However, it does require the involvement of teachers, mentors, managers, and leaders to understand how to use such a principle.

In a separate paper, Ayal et al.[2] add some additional perspective on how to advance interventions to prevent unethical behavior. The authors start by reminding the reader of the dilemma faced by a dishonest person. They are tempted by the profit of unethical behavior as well as the desire to be seen as moral person. The dissonance or discomfort from this dilemma leads a person to seek ways to justify their behavior so the dissonance will go away.

Ayal, Gino, Barkan, and Ariely et al. propose three principles to guide interventions and policy. They call it REVISE, taking the first two letters of remind, visible, and self-engagement:

1. Reminding

Research has demonstrated that "people often take advantage of gray areas," and thus if they are reminded in subtle cues about the saliency of being ethical, they will not be as likely to justify dishonesty. The above experiment of signing forms illustrates this principle.

2. Visibility

Research also has indicated that when people work alone, they are more likely to "lower their moral shackles," and thus prevention needs to **make visible** monitoring by peers and other forms of restricting anonymity to maintain adherence to norms. In one office experiment, payment for coffee increased threefold when a picture of eyes was placed over the collection jar.

3. Self-Engagement

People say being ethical is an important aspect of who they are, but then they often turn around and violate rules without thinking about the consequences. They believe people need reminders to resist temptation and help to build one's **self-engagement**.

They sum up their proposal by saying, **Reminding** mitigates gray areas that blur the ethical code, and **Visibility** mitigates anonymity and the possibility of slipping further down the slope. Since people want to believe they are honest, external reminders to resist temptations can help a person be **self-engaged**.

Their paper concludes with some examples of how it can be applied with tax compliance, shoplifting, handicapped parking, and bribery.

I believe it is worthwhile for instructors, mentors, managers, and leaders to incorporate REVISE principles in implementing day-to-day activities that require honest behavior. The RCR field needs to pay attention to the research that social psychologists are conducting on dishonesty and honesty. This research is describing relevant components of integrity rather than just urging integrity.

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ORI Welcomes Dr. Julia Behnfeldt, Presidential Management Fellow

ORI is fortunate to have been selected by Julia!

Upon graduation from The Ohio State University College of Medicine with a PhD in biomedical sciences/cancer biology, Julia was awarded a Presidential Management Fellowship (PMF). The PMF is a two-year training and development program that places recent graduates within various government agencies.

When asked why she chose ORI for her placement, she said she knew it was the place she wanted to be based on her education and personal experiences with research integrity in graduate school. As a student in a journal-club seminar, she detected what appeared to be a manipulated image while presenting an assigned article for the class. As a junior researcher, she was initially hesitant to report her concern to the professor leading the course. Luckily, the professor supported her finding, and they reported their observation to the journal. Eventually, the journal published a corrigendum on the article. The experience opened Julia's eyes to the lack of training graduate students receive in detecting and reporting potential research misconduct.

During her fellowship, Julia will have responsibilities in the Division of Education and Integrity and the Division of Investigative Oversight.

Julia's thesis research focused on understanding pathways that regulate global chromosomal stability and how those pathways are disrupted in cancer. Additionally, she examined telomere maintenance mechanisms, the key to cancer immortality, in various cancer subtypes.

In her spare time, Julia enjoys long-distance running. She has run two full marathons and eight half marathons. She is training for the Marine Corps Marathon in October 2016. She is an avid baker and enjoys making cakes and other sweets for her friends and family.

Julia and her husband recently moved from Ohio and are busy settling into D.C. They are enjoying visiting the Smithsonian museums and exploring the hiking trails in Rock Creek Park. As baseball fans, they are excited to attend their first Nationals game.

Sandra Titus, PhD, retires from ORI

We recently sat down with Dr. Sandra Titus, a longtime ORI employee, and asked her to reflect on her career and her recent retirement.

1. What did you do at ORI?

I was hired to develop and manage the ORI research agenda. We first met with everyone in ORI and discussed the types of research that would be helpful for ORI and helpful to the developing field. Three areas were identified as the most critical ones to study. ORI needed to learn the extent of research misconduct, how RIOs were doing in handling cases and preparing whistleblowers, and what institutions were doing to educate everyone on research misconduct and promoting mentoring.

In addition, over the years I edited the ORI newsletter, reviewed institutions' policies for handling allegations of research misconduct, organized conferences, and spoke at many of them on RCR topics.

2. What did you do before you worked for the government? How long have you worked in the government?

My first career was in healthcare delivery. I worked as an RN in acute care, public health, nursing education, and crisis intervention before I went back to school to get my PhD.

After I received my MS in Public Health and my PhD in Family Social Science from the University of Minnesota, I taught research methods in the medical school and graduate school and conducted policy research on access to health care. This led to a position as associate research director at Minneapolis Children's Medical Center, where I was hired to help build their research agenda and have oversight over grants and the Institutional Review Board (IRB). I administered the IRB for five years and became very interested in the development of regulatory policies and procedures. Hence, I worked hard to get a job interview at the Food & Drug Administration (FDA). I worked for the government for 21 years. I first spent seven years at FDA before joining ORI staff.

3. What are you most proud of accomplishing in your time at ORI?

I am most proud of what the intramural research program was able to study and complete. (See intramural completed studies link http://ori.dhhs.gov/studies-completed.)

One of the hurdles to understand about conducting government research, in contrast to academic research, is that the government oversight process is complex and requires patience and persistence. I worked with other researcher teams who were as interested as I was in conducting the studies.

The best part of doing research is the sense of discovery when you start to analyze. We completed all the studies we had planned to do. I worked with all the team members to get key findings submitted to peer review, deal with reviewer questions and concerns, and get the study results published.

4. We would like you to give us an update about what you have been doing in retirement. What adventures have you taken? Do you miss ORI?

A week after I retired in July, I moved from Maryland to Minnesota. I packed up my house and drove from Maryland to Minnesota, listening to my IPod's directions on how to avoid Chicago.

I moved to Northfield, Minnesota, to be closer to family. I am spending time with my three-year-old granddaughter and seeing the world through her eyes. She is eager, quite persuasive, and full of energy, and I feel fortunate to be able to be more involved.

In the fall I am planning a trip to Tanzania to see more animals. I never thought much about animals before going to South Africa, but I became hooked on how awesome it is to see and photograph them on the open plains. A safari is like a treasure hunt.

I miss many of the people I have known over the years. Robin Parker, Cyndi Ricard, Kay Fields, and John Krueger have been great colleagues and friends. I give a shout out particularly to Larry Rhoades, because he was a wise DEI director who supported the development of his staff and the intramural research program.

5. What do you think is the most pressing need in the field of research integrity?

Research on how to prevent cheating is the most pressing issue. We know that all people can cheat on occasions, and therefore, we need to know more about what can be done to prevent it. This has to take into account that many individuals have grown up in systems where cheating in college was common.

Since ORI has a regulatory role with institutions, we also need research on how institutions are promoting integrity in their efforts to educate their

population and develop institution-wide data integrity standards. This is an especially important issue related to the need for institutional involvement in helping to deal with the irreproducibility of research.

6. What advice might you have for someone assuming your position in ORI?

Consult with coworkers in ORI to develop some research seed ideas. Spend time learning the related social psychology, anthropology, and public health research field, and work with a team of researchers to develop your research design.

Research on research integrity is studying how people do things in practice – their behavior – not about opinions.

7. What has changed most since you joined ORI?

When I joined ORI there were about 50 to 75 individuals in the country conducting research or able to speak broadly about research integrity. The field has grown tremendously in 15 years, with hundreds of researchers in the US and internationally. The field is now so large that it is difficult to read all of the papers published even on one topic.

8. What would you like to say to all your colleagues in research institutions who share your passion for RCR?

There is no course that can teach honesty – because honesty is developed much earlier in life. One's early personal life and role models determine one's likelihood to cheat. If someone has grown up in a climate of lying, cheating on exams, copying others' answers, and taking credit for others' work, that person will not be influenced by such a course.

Most RCR education, training, and instruction result in crash courses on rules, guidelines, ethical principles, and expectations for researchers in a set of nine or ten topics. It is a Band-Aid approach. RCR should be more than a ten-hour regulatory hurdle or getting boxes checked.

Furthermore, requiring and formalizing it has taken the responsibility away from the mentors. In fact, research found that mentors often felt RCR was the institutions' responsibility (see Final Report on Mentors and Advisors Roles in Training PhDs 2009 (pdf)).

The authentic RCR effort is really about creating a culture – a code of life, a code of science, a code of acceptable behavior. Institutions should be more introspective when teaching good scientific methods versus mere compliance, and then in carefully selecting their teachers.

9. How do you create an institutional culture?

Trainees need to see that their institutional culture has integrity for them to care about a required course. A RIO is a key educational person who can discuss the need and importance of integrity of data and how to have a discussion with him on reporting research. The RIO also can discuss efforts that are made to protect whistleblowers and deal with retaliation. The RIO needs to have an open door policy and be willing to discuss hypothetical cases so a complainant learns the type of information a RIO needs to be able to consider reporting it. Leaders need to champion mentors and support and reward their efforts.

When a formal RCR course is developed, it should be taught by research scientists rather than by ethicists, lawyers, and other non-scientists. If instructors lack the actual research background, they lack understanding of the scientific methodologies where shortcuts could lead to misconduct. Research faculty need to be put in charge of RCR classes, but even better, they need to incorporate the content while they work with their mentees.

RCR is best taught by the mentor in the lab and in an ongoing manner.

COMMENTARY

International Cultural Integrity and Honesty

Sandra Titus, PhD

If I were considering participating in international research, I would try to find out as much as I could in advance about a country, and particularly how they govern themselves. I would want to know about their rules and requirements to protect myself. I also would want to understand how the country and institutions define and handle research misconduct and educate scientists. But more than the legal perspectives, I would want to try to understand how scientists conduct research in that country, how they work together, what their norms are about sharing data, deciding on team leadership, and authorship how they evaluate reliability of data, and what their perspectives are on social responsibility to science as a whole.

Programs preparing students and scientists to conduct research abroad need to develop educational programs that adequately describe cultural differences and ways to assess a potential colleagues' perspectives. Evaluating cultural perspectives is complex and an ongoing process. One has to learn to read other researchers' responses rather than assuming the world sees things and follows the same norms and rules as you try to do yourself.

It is hard work to find out much about honesty and how individuals in a culture view research integrity. The paper "Intrinsic honesty and the prevalence of rule violations across societies" provides a sobering view on how the culture you grow up in may impact on your behavior. A review of this paper would benefit all international researchers, even if the country they planned to work in was not reported in this paper.

Two behavioral economists, Gächter and Schulz, examine the relationship between large-scale cultural rule violations and their impact on individual behavior. http://www.ncbi.nlm.nih.gov/pubmed/26958830

This study may be of interest to RCR coordinators because of the increased globalization of research and the impact that might have on trainees. Their study involved two types of data collection. First, they gathered country-level data on 159 countries, derived from existing records on the level of corruption, tax evasion, and fraudulent politics in 2003. From this index they constructed their measure on the Practice of Rule Violations (PRV) for the countries. They then selected 23 countries that were representative of the world's distribution of PRV, which ranged from -3.1 to 2.0 with a mean of -0.7(sd=1.52). (A negative number represents fewer violations).

Since the researchers were interested in whether a culture's rules and level of corruption influenced younger people, they then conducted an experiment with 2568 students who, on average, were 21.7 and were roughly equally divided on gender. Students were selected to be the study participants because they would not have been old enough to influence the historical data collected on the country level indices of corruption.

Students were asked to roll a six-sided die twice and to report the first roll only. Die rolling was unobserved and unverifiable. Students knew they would be paid in money units of their country according to the roll of the die - except reporting they had rolled a six would earn nothing. In an honest pool an average claim would be 2.5 money units and in a fully dishonest unit they would claim five. Those students who reported rolling a six were considered to be the most honest because they received no money.

The researchers found that in societies with high levels of rule violations, the student population had fewer students who were perceived as being totally honest. Comparison between the levels of cheating above the normal distribution of the die toss found that populations from cheating cultures reported

overall higher numbers on their die tosses and were statistically more dishonest. In addition, the average claim of each population found a strong correlation of higher average claim for the rule violating culture's test takers. The last analysis tested for the number in each culture that reported rolling a six. There were fewer levels of highly honest people in the cultures that were more dishonest. Reporting a 5, which provided maximal earnings, was the only test in which their hypothesis was not supported. Not all people in a cheating culture cheated, and not all people in an honest culture were fully honest.

The authors believe their study results overall indicate that the students' intrinsic values were linked to their culture's level of violations towards rules. How we behave ethically is influenced by our cultures' norms on honesty and cheating.

The United States was not studied. Austria, Sweden, the United Kingdom, and Germany were cultures perceived to have low levels of rule violations and high levels of honest people.

In summary, the take home message from this paper is that integrity is contextual in each locality. This means the researcher must be prepared to continually assess the risk of dishonest behavior and work very hard at protecting data integrity. An individual would have to learn to work with others who may have very different norms and values. Thus, scientists would have to be prepared to take responsibility for the overall integrity of their research and be responsible for all aspects and components of the responsible conduct of research. An RCR course cannot teach this concept; it can merely remind the researcher about their commitment and about some of the inherent pitfalls they would need to avoid. A course also can help to raise awareness about why culture matters as well as help researchers anticipate the impact it will have on their research.

Additional Useful References:

Examining Core Elements of International Research Collaboration: Summary of a Workshop, NAP 2011
http://www.nap.edu/catalog.php?record_id=13192

Culture Matters: International Research Collaboration in a Changing World--Summary of a Workshop, NAP 2014,
http://www.nap.edu/catalog/18849/culture-matters-international-research-collaboration-in-a-changing-world-summary

Cultural challenges and international research integrity
Xavier Bosch, Sandra L Titus
DOI: http://dx.doi.org/10.1016/S0140-6736(09)60379-2

The Lancet
Volume 373, Issue 9664, 21 February 2009-27, Pages 610-12.
http://ori.hhs.gov/images/ddblock/cultural_challenges_and_their_effect_on_international_research_integrity.pdf

CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

Zhiyu, Li, Ph.D., Mount Sinai School of Medicine

Based upon the evidence and findings of an investigation report by the Mount Sinai School of Medicine (MSSM) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Zhiyu Li, former Postdoctoral Fellow, MSSM, engaged in research misconduct in research that was supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant R21 CA120017. ORI found that falsified and/or fabricated data were included in the following published papers, submitted manuscript, poster presentation, and grant applications:

- Li, Z., Fallon, J., Mandeli, J., Wetmur, J., & Woo, S.L.C. "A Genetically Enhanced Anaerobic Bacterium for Oncopathic Therapy of Pancreatic Cancer." *JNCI* 100(19):1389-1400, October 2008 (hereafter referred to as "*JNCI* 2008") (Retracted 02/2010).
- Li, Z., Fallon, J., Mandeli, J., Wetmur, J., & Woo, S.L.C. "The Oncopathic Potency of *Clostridium perfringens* is Independent of its □-Toxin Gene." *HGT* 20:751-758, July 2009 (hereafter referred to as "*HGT* 2009") (Retracted 03/2010).
- Li, Z., Fallon, J., Mandeli, J., Wetmur, J., & Woo, S.L.C. "Oncopathic Bacteriotherapy with Engineered C. *perfringens* Spores is Superior and Complementary to Gemcitabine Treatment in an Orthotopic Murine Model of Pancreatic Cancer." Submitted for publication in *Can. Res*. (hereafter referred to as the "*Can. Res*. Manuscript 2009").
- Li, Z., Fallon, J., Mandeli, J., Wetmur, J., & Woo, S.L.C. "Oncopathic Bacteriotherapy with *Cp/plc-/sod-/PVL* is Complementary to Gemcitabine Treatment for Pancreatic Cancer in Mice." Presented at the 12th Annual Meeting of the American Society of Gene Therapy, May 27-30, 2009.
- R21 CA120017-02
- R21 CA120017 Final Progress Report
- R01 CA130897-01
- R01 CA130897-01 A1
- R01 CA130897-01 A2
- R01 CA130897-01 A2 Supplemental Material
- R01 CA148697-01

The *JNCI* 2008 and *HGT* 2009 papers were retracted, and the *Can. Res.* Manuscript 2009 was withdrawn.

ORI found that the Respondent intentionally, knowingly, and recklessly engaged in research misconduct by falsely claiming to have generated recombinant *Clostridium perfringens (Cp)* strains, *Cp/sod-, Cp/sod-/PVL*, and *Cp/plc-/sod-/PVL*, to depict the effects of recombinant Cp strains on their ability to destroy cancer cells in a murine model, when these bacterial strains were not produced nor the data derived from them, and by falsifying histopathological data reported in fifty-seven (57) images in two (2) published papers, one (1) submitted manuscript, two (2) poster presentations, and seven (7) of Respondent's supervisor's grant applications and fabricating the corresponding nineteen (19) summary bar graphs that were based on those false images.

Specifically, Respondent trimmed and used portions of Figure 6 (right panel) of a draft R21 CA120017-01 grant application, representing an image of liver tumor two (2) days after injection of *Cp/plc-* bacteria, to represent unrelated results from different experiments in:

- Figures 5D and 7C (left panel), grant R21 CA120017 Final Progress Report
- Figure 6A, grant R01 CA130897-01
- Figures 9D and 17A (top left, middle, and right panels and bottom left panel), grant
- R01 CA130897-01 A1
- Figures 6D and 9C (left panel), grant R01 CA130897-01 A2

CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

- Figure 2A (left, middle, and right panels) in R01 CA130897-01 A2 Supplemental Material
- Figures 4D and 7C (left panel), grant R01 CA148697-01
- Figure 4D (left panel), *JNCI* 2008
- Figure 3A (left panel), *HGT* 2009
- Figure 1A (left, middle and right panels), *Can. Res*. Manuscript 2009
- Figure labeled "Intratumoral Bacterial Titers and Quantification of Tumor Necrosis" (top left panel), *AGST* 2009 Poster presentation 2

Respondent trimmed and used portions of Figure 6C of R21 CA120017-02, representing pancreatic tumor five (5) days after injection of *Cp/sod-* bacteria, to represent results from different experiments in:

- Figures 5E, 6E and 7C (right panel), grant R21 CA120017 Final Progress Report
- Figures 9E, 10E, and 13C (right panel), grant R01 CA130897-01 A1
- Figures 6E, 7E and 9C (right panel), grant R01 CA130897-01 A2
- Figures 4E, 5E and 7C (right panel), grant R01 CA148697-01
- Figure 4D (right panel), *JNCI* 2008
- Figure 3A (middle and right panels), *HGT* 2009
- Figure labeled "Intratumoral Bacterial Titers and Quantification of Tumor Necrosis" (top right and middle panels), *AGST* 2009 Poster presentation 2

Respondent trimmed and used a portion of a figure that was reported as mouse pancreatic tumor tissue treated with control liposomes in four (4) figures (Figure 6D in R21 CA120017 Final Progress Report, Figure 10D in R01 CA130897-01 A1, Figure 7D in R01 CA130897-01 A2, and Figure 5D in R01 CA148697-01), to represent results from mouse pancreatic tumor tissue not treated with control liposomes in:

- Figures 7C (middle panel), grant R21 CA120017 Final Progress Report
- Figure 13C (left panel), grant R01 CA130897-01 A1
- Figures 9C (middle panel), grant R01 CA130897-01 A2
- Figure 7C (middle panel), grant R01 CA148697-01
- Figure 4D (middle panel), *JNCI* 2008
- Figure entitled "Oncopathic Potency of *Cp/sod-/PVL* in Tumor-bearing Mice" row C (left panel), *AGST* 2009 Poster presentation 1

Respondent falsified at least four (4) and possibly eight (8) images by using and relabeling Figures 4A (left panel), 4B (right panel), and 4B (left panel) in *JNCI* 2008 and Figure 1B (center panel) of *Cancer Res*. Manuscript 2009, to represent different experimental conditions in Figures 3C (middle panel), 3B (left panel), 3C (right panel), and 3D (left panel) in *HGT* 2009 respectively.

Respondent trimmed and used portions of Figure 4E (right panel) in *JNCI* 2008, representing pancreatic tumor from mice injected with *Cp/sod-/PVL* bacteria, to represent mice injected with *Cp/plc-/sod-/PVL* bacteria in the following:

- Figure 2, row B (right panel), R01 CA130897 01 A2 Supplemental Material
- Figure 3, row D (right panel), *HGT* 2009
- Figure entitled "Intratumoral bacterial Titers and Quantification of Tumor Necrosis" (bottom right panel), *AGST* 2009 Poster presentation 2
- Figure 1, row B (right panel), *Can. Res.* Manuscript 2009

The Respondent also fabricated the resulting quantitative data in nineteen (19) summary bar-graphs based on the false histopathological images in:

- Figure 7C, grant R21 CA120017 Final Progress Report
- Figures 13C and 17B, grant R01 CA130897-01 A1

- Figure 9C, grant R01 CA130897-01 A2
- Figure 2A-B, grant R01 CA130897-01 A2 Supplemental Material
- Figure 7C, grant R01 CA148697-01
- Figures 4A, B, D, and E, *JNCI* 2008
- Figures 3A-D, *HGT* 2009
- Figure 1C, *Can. Res.* Manuscript 2009
- Figure entitled "Oncopathic Potency of *Cp/sod-/PVL* in Tumor-bearing Mice" graph (C) in *AGST* 2009 Poster presentation 1
- Figure entitled "Intratumoral Bacterial Titers and Quantification of Tumor Necrosis" top and bottom row graphs in *AGST* 2009 Poster presentation 2

The following administrative actions have been implemented for a period of five (5) years, beginning on July 3, 2016: (1) Respondent is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 C.F.R. Part 376 *et seq*) of Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations"); and (2) Respondent is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Andrew R. Cullinane, Ph.D., National Institutes of Health

Based on Respondent's admission, an assessment conducted by the National Institutes of Health (NIH), and analysis conducted by ORI in its oversight review, ORI found that Dr. Andrew R. Cullinane, former postdoctoral fellow, Medical Genetics Branch, National Human Genome Research Institute (NHGRI), NIH, engaged in research misconduct in research supported by NHGRI, NIH.

ORI found that Respondent engaged in research misconduct by reporting falsified and/or fabricated data in the following two (2) publications and one (1) submitted manuscript:

- *Am. J. Hum. Genet.* 88(6):778-787, 2011 (hereafter referred to as "Paper 1")
- *Neurology* 86(14):1320-1328, 2016 (hereafter referred to as "Paper 2")
- "*RAB11FIP1*, Mutated in HPS-10, Interacts with BLOC-1 to Mitigate Recycling of Melanogenic Proteins." Submitted for publication to *The Journal of Clinical Investigations, Cell, Nature Biology, Molecular Cell, and Nature Genetics* (hereafter referred to as "Manuscript 1")

ORI found that Respondent knowingly falsified and/or fabricated data and related images by alteration and/or reuse and/or relabeling of experimental data. Specifically:

- in Paper 1, Respondent falsified and/or fabricated the results in Figure 3C by using the same gel images to represent expression of PLDN in fibroblasts and melanocytes
- in Paper 2, Respondent falsified and/or fabricated the results in Figure 2A by erasure of a band in the blot image for LYST/CHD-4 that was present in the original data
- in Manuscript 1, Respondent falsified and/or fabricated the results in Western blot data by reuse and relabeling, duplication, and/or manipulation in Figures 2B, 2D, 2E, 3A-C, 4C, 4E, 4G, 5B, 6A-C, 7A, 7D, 7G, 7J, and Supplemental Figure 3, and Respondent falsified and/or fabricated the results by reuse and relabeling of centrifuge tubes to represent different experiments in Figures 1D, 7C, 7F, 7I, 7L, and Supplemental Figure 2

CASE SUMMARIES OF RESEARCH MISCONDUCT FINDINGS

Dr. Cullinane has entered into a Voluntary Settlement Agreement with ORI and NIH, in which he voluntarily agreed:

(1) to have his research supervised for a period of three (3) years beginning on July 22, 2016; 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, the institution employing him must submit a plan for supervision of his duties to ORI for approval. The plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he will not participate in any PHS-supported research until a plan for supervision is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that for a period of three (3) years beginning on July 22, 2016, any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on July 22, 2016; and

(4) as a condition of the Agreement, Respondent agreed to the retraction or correction of:

- *Am. J. Hum. Genet*. 88(6):778-787, 2011
- *Neurology* 86(14):1320-1328, 2016