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Office of Research Integrity

NEWSLETTER

The *ORI Newsletter* is published quarterly by the Office of Research Integrity, Office of the Assistant Secretary for Health, Department of Health and Human Services, and distributed to applicant or awardee institutions and PHS agencies to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research. Please duplicate and circulate this newsletter freely. An electronic copy is available on the ORI home page at http://ori.hhs.gov.

IN THIS ISSUE

ORI's Research on Research Integrity (RRI) Granting Program

In 2013, the Assistant Secretary for Health, Dr. Howard Koh, decided that ORI would be better able to meet their educational and research missions if ORI could administer its own research granting program. He understood the growing urgency to learn more about the causes of research misconduct as well as ways to prevent it and promote the responsible conduct of research (RCR).

For the past 10 years, ORI has sponsored a similar granting round through various institutes at the National Institutes of Health. However, this new granting authority meant that ORI could determine the research foci and select reviewers from the RCR field of researchers. ORI received 19 proposals and awarded $1.2 million.

ORI is pleased to announce the five researchers who received the awards:

- **James M. DuBois, Ph.D.**
  Saint Louis University
- **Daniele Fanelli, Ph.D.**
  The University of Edinburgh
- **Eric Fong, Ph.D.**
  The University of Alabama in Huntsville
- **Wayne T. McCormack, Ph.D.**
  University of Florida
- **Camille Nebeker, Ph.D.**
  University of California, San Diego

Three proposals focused on applied educational evaluations: Dr. McCormack's team will focus on developing a team-based ethical learning curriculum that will then be tested in three programs. Dr. Nebeker's emphasis is on developing and evaluating research competencies with Hispanic paraprofessionals who serve as research data collectors. Dr. DuBois is developing an instrument to assess the impact of a remediation program on researchers who violate research standards and rules.

Two of the research proposals are hypotheses driven and examine problem areas in RCR research. Dr. Fanelli is focusing on whether reported research results are becoming more exaggerated and fabricated in the world, and if so, are such results occurring in certain fields or in certain countries. Dr. Fong is focusing on measuring the extent of and reactions to the practice of honorary authorship and coercive citation practices in academic medicine and grant writing.

Abstracts that appear in this newsletter describe each project more fully. We look forward to the findings that the five teams will generate.

2014 Granting Round

ORI anticipates having an RRI granting round next spring. One

(See Granting Program, page 2)

Validating Outcome Measures for Remediation of Research Wrongdoing

James M. DuBois, Ph.D., Saint Louis University

Our team developed the Restoring Professionalism and Integrity in Research (RePAIR) program—now known as the *Professionalism and Integrity* (P.I.) program—with funding from a National Institutes of Health administrative supplement to the Washington University in St. Louis Clinical and Translational Science Award (CTSA). The P.I. Program provides intensive professional development education for investigators who have engaged in wrongdoing or unprofessional behavior. Our current project will address three challenges that exist when evaluating the outcomes of remediation efforts.

First, we will determine the measures to be used to assess the outcomes of remediation programs. Past research suggests that the ideal measures would assess self-serving biases and the use of sense-making strategies in the context of doing research. Such measures also need to be suitable for use with investigators who speak English as a second language. Accordingly, our first aim is to establish the validity and reliability of the *How I Think about Research* (HIT-Res) test. This test assesses four kinds of self-serving biases in a research context, and the *Professional Decision-Making Measure* (PDM).

Second, we will gather and compare normative data (mean scores and standard deviations) from P.I. Program participants. We will also collect and compare these data against a control group of 400 heterogeneous researchers working in the United States who have never been investigated for compliance failures or wrongdoing.

Third, we will assess the outcomes of the P.I. Program using pre- and post-tests on the HIT-Res test and PDM. This assessment will enable us to evaluate the effect that the P.I. Program training has on levels of self-serving bias and on the use of sense-making strategies.

While our project's focus is on assessing the outcomes of remediation education, the instruments and scores generated by the project will be valuable to the larger world of responsible conduct of research instruction.

James DuBois, Director of the P.I. Program, will lead the research

(See Outcome Measures, page 3)

Granting Program *(from page 1)*

thing ORI learned in the process, which will be corrected next year, is the need for ORI to hold a general webinar and discuss the purpose of the granting round and the scoring factors. Many proposals did not respond effectively in describing how their proposal was significant, or unique, or would be tackling one of the elements in ORI's Funding Opportunity Announcement (FOA). In describing the actual research plan, an applicant needs to consider ways to address FOA foci and FOA scoring criteria. The methods are of course very important in the proposal and should be planned and, when possible, piloted beforehand to determine whether the methods are implementable. Also, many proposals did not put forward a realistic budget with plausible numbers or convincing justification.

Because the government has been running on a continuing resolution, ORI often does not know what its working budget will be until late spring. Since budget cuts are likely, one might realistically anticipate that ORI's maximum award size in the future will be set at $150,000 per year. And a second year of funding is never guaranteed. We expect to be posting a FOA the first of the year, contingent on anticipated funding.

ORI Thanks

RRI Review Committee Chairs

Brian Martinson
Nick Steneck

&

RRI Grant Reviewers

Alison Antes
Amy Campbell
Xin He
Zubin Master
Ken Pimple
Dena Plemmons
Adil Shamoo
Wendy Williams

Unraveling the Causes of Bias and Misconduct

Daniele Fanelli, University of Edinburgh, and John P.A. Ioannidis, Stanford University

Are false, exaggerated and fabricated studies becoming more frequent? Which fields, countries, institutions, and individuals are at greater risk, and why? This project will help answer these questions by reanalyzing data from published meta-analyses, in order to identify factors that push researchers to select, embellish, and falsify their findings.

The likelihood of researchers engaging in irresponsible and fraudulent practices is hypothesized to depend on a hierarchy of causes. Their reasons range from the competitiveness of researchers' environment to characteristics of their personality, passing through the rigor of their methodologies, and the level of social control exerted by their collaborators. These factors might interact with each other, and their effects may vary in intensity across fields and countries. Measuring the relative importance of these factors could, and should, provide an empirical basis to guide initiatives aimed at preventing and correcting scientific bias and misconduct.

Currently, most quantitative evidence about risk factors for bias and misconduct comes from surveys and interviews. These first-person accounts should be cross-checked and integrated with direct assessments of the scientific literature to yield conclusive tests and inform specific policies. After all, the scientific literature is where the effects of fabrication, falsification, questionable practices, and unconscious biases are ultimately felt. We recently developed a protocol to assess whether empirical studies are likely to report exaggerated and biased effects. We used this protocol in a small study (Fanelli & Ioannidis, 2013). In this project, we will apply the method we developed to a large body of literature and will test the effect of various characteristics of studies and authors.

We will sample at least 1,000 meta-analyses from all fields of the biomedical and social sciences, extract data on the primary studies appearing in each of these meta-analyses, and calculate a standardized measure of how each primary study had over- or under-estimated the effect it was trying to measure. Using a multi-level meta-regression approach, we will then verify how this parameter (and related measures, here omitted for brevity) varies over time and with characteristics of discipline, methodology, country, institution, career level, and gender of authors. This data set could also be used to examine the effects of other hypothesized risk factors in future research.

These results will offer a vital complement to survey data and qualitative research on bias and misconduct. The findings also will help to improve our understanding of these problems, inform new policies, and guide future research and initiatives.

Reference

Fanelli, D., & Ioannidis, J. (2013, August 27). U.S. studies may overestimate effect sizes in softer research. *Proceedings of the National Academy of Sciences* [PNAS], *110*(37), 15031–15036. doi:10.1073/pnas.1302997110. Epub 2013, August 26.

Outcome Measures

(from page 2)

team, with John Chibnall, Raymond Tait, and Jillon Vander Wal—all P.I. Program faculty at Saint Louis University—serving as co-investigators. Michael Mumford will serve as a consultant. A unique feature of this project team is that all key personnel hold doctoral degrees in a specialty of psychology, including clinical, general experimental, industrial-organizational, and social psychology.

" 'Normal science' means research firmly based upon one or more past scientific achievements, achievements that some particular scientific community acknowledges for a time as supplying the foundation for its further practice."

Thomas S. Kuhn
(1922-1996)

Honorary Authorship and Coercive Citations

Eric Fong, Ph.D., University of Alabama in Huntsville

This project expands our original work on manipulative citation practices (Wilhite & Fong, 2012) beyond social science and business disciplines to physical science, biological science, engineering, medicine, and nursing disciplines. Additionally, we examine the pervasiveness of honorary authorship, coercive citations, and gratuitous citations in both grant proposals and publications in all of the above disciplines, including business and social sciences. Thus, we will have a comprehensive mapping of the pervasiveness of honorary authorship, coercive citations, and gratuitous citations across the academic universe. Consistent with previous work in this area, we not only measure the incidences of manipulation, but the incentives that induce these activities, scholars' opinions of manipulation, and some consequences of these practices.

Research funding and journal space are constrained, so these factors create competition between scholars for funding and publication. Modeling this competition in a game-theoretic framework, we generate a series of hypotheses about manipulation that we will test empirically using data from a nationwide survey of scholars in all of these fields. This data collection process, designed to generate thousands of responses, becomes a significant part of the effort. With this breadth and depth of information, we measure the extent of, incentives for, and reactions to, citation and authorship manipulation. It is our intent to raise awareness of these issues through publishing our findings. We plan to provide more complete information for responsible conduct of research (RCR) training modules, better target RCR audiences, and provide information that may allow for the better design of policies to reduce such abuses.

Reference

Wilhite, A. W., & Fong, E. A. (2012, February 3). Coercive citation in academic publishing. *Science*, *335*(6068), 542–543.

Team-Based Learning for RCR Education

Wayne T. McCormack, Ph.D., College of Medicine, University of Florida

The overall goal of this project is to validate a team-based learning (TBL) responsible conduct of research (RCR) curriculum that is adaptable to different science and engineering disciplines and to different learners, portable to different institutions, deliverable using discussion facilitation skills familiar to many instructors, and demonstrated to have a positive impact on ethical decision-making (EDM) skills. A preliminary study of TBL in RCR education at the University of Florida (UF) revealed that learners used more helpful reasoning strategies and showed more attention to the social dimensions in their decision making after TBL instruction. Therefore, learners improved in two EDM domains. It is important to note that most of the detrimental effects on EDM reported for other forms of RCR instruction were not observed after TBL instruction. This project will test the hypothesis that EDM abilities, both short term and long term, can be improved through the use of a TBL RCR curriculum.

The project has three objectives:

1. Revise the TBL RCR curriculum to incorporate a moral method for decision making and improve case design to better support EDM. The TBL RCR modules will each be designed to have specific learning objectives that address the most important ethical issues in the nine ORI-recommended instruction areas.
2. Evaluate the effectiveness of the TBL RCR curriculum in science and/or engineering programs at four universities using a validated test of EDM in pre-, post-, and 12-month post-course follow-up testing of learners.
3. Assess student perceptions of the TBL RCR curriculum and its impact on EDM using a mixed-method quantitative and qualitative approach.

Our project team includes investigators from the UF College of Medicine (Wayne McCormack and

(See Team-Based Learning, page 5)

Evaluating RCR Training with Paraprofessional Research Staff

Camille Nebeker, Ph.D., University of California, San Diego (USCD)

Community Health Workers (CHWs) and *Promotores* have proven effective in providing health care and resources for hard-to-reach populations for over 30 years. And now, these paraprofessional staff help to conduct community-based health *research*. These members of the community assist academic researchers with study recruitment, informed consent, data collection, and research management. But these critical members of the research team have had little or no formal academic training in research design or scientific methodology. They also are largely overlooked in mandated Responsible Conduct of Research (RCR) education programs.

The lack of consistent and basic training in scientific methods and human research protections may contribute to decisions in the field that compromise the integrity of research studies. For example, *Promotores* may be asked to randomly assign subjects to different conditions of a research intervention. Lacking sufficient knowledge in research design and the purpose of random assignment, a *Promotora* may assign by convenience to provide what she believes may benefit the subject and not consider the impact on data integrity. Or the *Promotora* may not understand the significance of research methods that require blinded conditions or constraints. Likewise, because of the *Promotores'* social relationships with members of the community, there is the potential that the intent of the informed consent and the ideal outcome of complete disclosure and voluntary participation may be compromised.

The need to provide research ethics training for paraprofessional research staff led to developing a National Institutes of Health-supported training for CHWs/*Promotores* on human research ethics called *Training in Research Ethics and Standards* (TRES) (*http://nationalethicscenter.org/tres*). It also led to the development of a tutorial, supported by ORI, on *Basic Research Concepts* (BRC) (*http://ori.hhs.gov/education/products/sdsu*).

Our evaluation will assess the extent to which these two educational interventions are effective in developing research literacy and competencies needed to carry out a research protocol. The study objectives will be carried out over a two-year period. Year 1 will focus on developing and testing a *Research Readiness Inventory* (RRI) to measure research competencies in paraprofessional staff. Year 2 will use the RRI to assess the extent to which the educational interventions influence research competency test scores.

Camille Nebeker and colleagues Mike Kalichman (UCSD Research Ethics Program) and Sheila Castaneda and Greg Talavera (San Diego State University's Institute of Behavioral and Community Health) will be involved in designing the instrument and assessing the effectiveness of the research integrity training for paraprofessional researchers in community-based Latino health research.

Team-Based Learning *(from page 4)*

Cynthia Garvan), UF College of Engineering (Erik Sander and William McElroy), Pennsylvania State University College of Medicine (Michael Verderame, Paul Haidet, Rebecca Volpe, and Joshua Crites), the University of Alabama at Birmingham (UAB) Graduate School (Jeffrey Engler), the University of Oklahoma (Shane Connelly), and Albert Einstein College of Medicine (Victoria Freedman). The five study sites for implementation and testing of the TBL RCR curriculum follow: the Ph.D. programs in biomedical sciences at UF, Pennsylvania State, and Albert Einstein, the engineering graduate program at UF, and the graduate school at UAB.

The final product will be a TBL RCR curriculum that can easily be disseminated to and used by scientists and engineers involved in RCR education at other institutions.

> *"The successful person makes a habit of doing what the failing person doesn't like to do."*
>
> **Thomas Edison**
> (1847-1931)

Institutional Annual Report on Possible Research Misconduct

In mid-December, the Office of Research Integrity (ORI) will send an email notification to over 6,000 institutions that receive Public Health Service (PHS) funds to remind their institutional officials about the process to use to report their 2013 Annual Report on Possible Research Misconduct. The electronic submission is made through the ORI web site at *https://ori.hhs.gov/arprm/Login.php*. The process can be initiated on January 1, 2014, and must be completed no later than March 1, 2014.

The institutional signing official is required to report all allegations of fabrication, falsification, and/or plagiarism received by the institution, including allegations that do not proceed to the inquiry or investigation phase (see PHS-6349 at *http://www.hhs.gov/forms/PHS-6349.pdf*). ***Note:*** This report does not cover regulated research under the jurisdiction of the Food and Drug Administration.

In addition, to ensure that the institution remains eligible for PHS research funding, the institution must have an administrative policy in place for handling allegations of research misconduct. That policy must comply with PHS regulation 42 C.F.R. Part 93.

To assist institutions in creating or evaluating their policy, ORI plans to post a suggested checklist that outlines the sections of PHS regulation 42 C.F.R. 93 and that may be helpful in developing or revising an institution's policy for handling allegations of research misconduct.

For further information and assistance, please contact the ORI Assurance Program Specialist, Robin Parker, at robin.parker@hhs.gov or call (240) 453-8400.

Case Summary

Pratima Karnik, Ph.D.
Case Western Reserve University

Based on the admission of the Respondent, ORI found that Dr. Pratima Karnik, Assistant Professor, Department of Dermatology, Case Western Reserve University (CWRU), engaged in research misconduct in research submitted to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH), in grant application R01 AR062378.

ORI found that the Respondent engaged in research misconduct by plagiarizing significant portions from research grant application R21 AR061881 that she had reviewed for NIAMS, NIH, and inserting that text into her submitted grant application R01 AR062378-01. Respondent also plagiarized significant portions of text from the following scientific articles and one U.S. patent application available on the Internet:

- *BMC Med Genomics* 4:8, 2011
- *J Am Col. Cardiol* 52:117-123, 2008
- *Nature* 457:910-914, 2009
- *J Autoimmun* 29:310-318, 2007
- U.S. Patent Application No. 20090047269 (published Feb. 19, 2009)
- *Toxicol Pathol* 35:952-957, 2007
- *BMC Med Genomics* 1:10, 2008

(See Case Summary, page 7)

Case Summary *(continued)*

- *Open Systems Biology Journal* 1:1-8, 2008
- *Endocrinology* 146:4189-4191, 2005.

Dr. Karnik has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of two (2) years, beginning on July 22, 2013:

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

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

(3) to exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

"There is not a discovery in science, however revolutionary, however sparkling with insight, that does not arise out of what went before. 'If I have seen further than other men,' said Isaac Newton, 'it is because I have stood on the shoulders of giants.'"

Isaac Asimov
(1920-1992)

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