U.S. Department of Health and Human Services • Office of the Secretary • Office of the Assistant Secretary for Health

VOLUME 19, NO. 4 HTTP://ORI.HHS.GOV SEPTEMBER 2011

Office of Research Integrity

NEWSLETTER

The *ORI Newsletter* is published quarterly by the Office of Research Integrity, Office of the Assistant Secretary 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.

IN THIS ISSUE

Promoting Integrity in Clinical Research

Sandra Titus, Ph.D.; John Krueger, Ph.D.; and Peter Abbrecht, M.D., Ph.D.

Clinical research is important to society since it has the potential to personally affect and/or benefit the individual. In 2008, the federal government invested $30 billion in biomedical research through the National Institutes of Health (NIH).[1] Fourteen percent of these funds involved clinical research. This article highlights some of the ways clinical research studies have been compromised, as revealed from ORI's collective experiences. This focus will potentially promote better preventive strategies and sharpen the oversight done by research teams and institutions.

Over the past 20 years, ORI has made findings of research misconduct in 69 clinical cases. Principal investigators (PIs) accounted for a fifth of the cases (21%), whereas the majority of cases (79%) involved non-professional staff—including study nurses, coordinators, data managers, clinical monitors, lab personnel, technicians, research assistants, graduate students, and postdoctoral fellows in training.

(See Promoting Integrity, page 2)

D.C. District Court Upholds HHS's Research Misconduct Findings and the Imposition of a Seven-Year Debarment

Jo An Rochez, J.D., Senior Attorney, Office of the General Counsel, U.S. Department of Health and Human Services, and John Dahlberg, Ph.D., Director, Division of Investigative Oversight, ORI

On July 13, 2011, the U.S. District Court for the District of Columbia (District Court) granted HHS's summary judgment motion and upheld two decisions. The first was the Administrative Law Judge's (ALJ's) decision finding that the researcher, Scott J. Brodie, Ph.D., D.V.M. (Respondent), committed multiple acts of research misconduct. The second was the HHS debarring official's decision to debar Brodie for seven years. The District Court rejected all the Respondent's arguments, including his claims that the ALJ used the wrong culpability standard and failed to establish a standard of care.

Background

The Respondent, a molecular virologist and board-certified anatomic pathologist, was employed by the University of Washington (UW) as a Research Assistant Professor and Director of the Retrovirology Pathogenesis and Molecular Virology Laboratories. While at UW,

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Promoting Integrity *(from page 1)*

ORI has observed that the different types of clinical research have different areas of vulnerability that can compromise the research endeavor: [2]

1. **Clinical or treatment trials** involve conducting experimental medical procedures, developing drugs, and testing new treatments for efficacy and safety. The major vulnerability in clinical trials has been predominately at the time of entry into the study. Pressures for rapid enrollment, along with incentives and bonus payments for each enrolled subject, may influence staff, much the same way that other conflicts of interest are known to influence outcomes.[3,4,5]

   Although most enrollment pressures have involved junior staff, in one of ORI's early cases, wholesale falsifications were made by a physician's staff, at his direction, because he was sympathetic to many of his patients not being able to otherwise afford proper treatment.

2. **Survey-based research** focuses on studies that gather information for subsequent analyses. Such studies can focus on the psychological impact of external events, subject response to certain therapeutic interventions, and prevention trials. The time of vulnerability in survey research predominately involves subject interview manipulation or substitution of specimens, such as urine or blood.

   A blatant form of interview manipulation termed "curbstoning" refers to an interviewer "sitting at the curb" and making up answers and interviews rather than seeking out hard-to-find subjects or going to dangerous neighborhoods to conduct followup interviews.[6,7]

3. **Epidemiology studies** identify risk factors associated with disease or related phenomena.[8] Epidemiologic study designs require extensive data collection and analytic effort, incorporating data from multiple sources (e.g., questionnaires, medical records, interviews, lab reports, and observations) over a significant time frame. Vulnerable points for research misconduct (e.g., falsifying data) in epidemiology studies occur at all times during the study data collection and analysis.

Prevention Strategies

The diversity and redundancy of certain records provide a significant burden for anyone contemplating falsifying the records, since the numerous records also provide significant opportunity for oversight. Allegations of clinical research misconduct are initiated not only after audits, but also as a result of inconsistencies in data noted during changes in personnel. Preventive measures should exploit the multiple sources and occasions for review:

1. **Safeguard Enrollment:** ORI considers the manipulation of enrollment criteria to be research misconduct. Protocol forms should be simple with a clear designation of the required information. Alterations on data forms must be done by striking through the original entry, initialing, and then dating the new entry. Events that appear to be merely "protocol violations" can become misconduct if they are linked with the falsification of forms, because these are part of the research record. Any staff member whose primary responsibility is to increase enrollment in any study must understand the distinctions and the ramifications.

2. **Avoid Compromises in Record Keeping:** Records should be kept in a secure locked space, especially when the information is protected under the HIPAA Privacy Rule.[9] In studies with ongoing data collection, the individual who collects the data should not be the same person who enters the data into the system. This precaution can eliminate an opportunity for data manipulation.

3. **Use FDA Standards on Good Clinical Practice (GCP):** The FDA's GCP is the gold standard on how to structure data collection to support the study findings and be prepared for an audit. This guidance includes having records to indicate location of source data, case reports, protocol adherence, locked records, and signed informed consent (see also *http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133569.htm*).

4. **Conduct and Report Audits:** Informing team members of a quality control plan, as well as conducting unscheduled audits,

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will create the awareness that records will be monitored and scrutinized. In addition, post-audit follow-up should be standard in a clinical study, and publications of trials would gain credibility if audit details were submitted and included in publications.[10]

5. **Training of Non-Research Staff:** Treatment trials may involve junior staff members who have limited background in research and who often work independently of senior staff. In a previous study of ORI clinical cases, junior staff were in charge of data collection (n = 29, 74%) that was combined frequently with obtaining informed consent (n=11, 28%) or recruiting subjects (n=9, 23%).[11] The importance of training non-research staff cannot be overemphasized.

6. **Maintain a "Physical Presence" in the Research Project:** Research misconduct is more likely to occur when PIs are uninvolved and are not setting standards for data collection with their research group or students.[12] The PI and other supervisors must maintain strong communication with staff and students and enforce adherence to research protocol. The social context can deter cutting corners and making mistakes as well as prevent research misconduct.

Clinical research is important and individuals and institutions should strive to ensure that research integrity is always at the forefront. We hope these comments on ORI's 20 years of dealing with misconduct in clinical research, and thoughts about how to prevent it in the future, will give readers information to apply to their own research program.

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Further Correcting the Literature: PubMed "Comments" Link Publications to PHS Research Misconduct Findings

John Krueger, Ph.D., Scientist-Investigator, DIO, ORI

Introduction

Ideally, publications that are the subject of ORI's findings of falsification, fabrication, or plagiarism are either corrected and/or retracted from the literature. However, correction of the literature involves participation of multiple parties, and once allegations arise, they often have conflicting priorities about what should be said and when that statement should occur.

Journals are eager to correct the literature as soon as possible. But they also need to be concerned about fairness and accuracy by not retracting prematurely. Coauthors want a public statement that exonerates the particular results they contributed to the research. Institutions, often pressured by their faculty to resolve matters quickly, need to be thorough in their fact-finding. Corrections published before institutional involvement (or

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Court Upholds *(from page 1)*

Dr. Brodie engaged in HIV/AIDS research projects that were supported by U.S. Public Health Service (PHS) funds. UW conducted a comprehensive investigation and, in 2003, concluded that Dr. Brodie had submitted or presented documents and data that contained images that he had intentionally falsified or fabricated. After extensive review of the evidence provided by UW, in September 2008, ORI made fifteen (15) findings of research misconduct against Dr. Brodie. ORI found that Dr. Brodie falsified over 100 figures in grant applications, progress reports, manuscripts, journal articles, and PowerPoint presentations related to persistent HIV replication in certain human cells. Detailed image comparisons demonstrated that Dr. Brodie repeatedly reused the same images and falsely labeled them as deriving from various body parts and/or he extensively digitally manipulated the images by adding or removing cells, inverting or flipping the images, or combining images and then falsely labeling them. Brodie requested a hearing before the Departmental Appeals Board. On January 12, 2010, the ALJ granted the Government's motion finding that Dr. Brodie "on a massive scale" submitted false data in the grant applications, presentations, and journal publications. The ALJ also found that the seven-year debarment period was reasonable.

District Court Ruling

Brodie appealed the administrative decision by filing a complaint in District Court on April 2, 2010, challenging the ALJ's decision and seeking a preliminary injunction (PI) to remove his name from the General Services Administration list of excluded parties. The District Court denied Dr. Brodie's PI motion on June 4, 2010, finding that Brodie failed to demonstrate either a likelihood of success on the merits or an irreparable injury. Both HHS and Dr. Brodie filed motions for summary judgment.

The District Court rejected Dr. Brodie's claims that the ALJ incorrectly applied a low standard of recklessness when determining whether he had committed the acts of research misconduct. Dr. Brodie alleged that the applicable regulation, PHS's pre-2005 research misconduct regulation, precluded a recklessness culpability standard and required a finding of knowing and intentional conduct. The Court pointed out that although the ALJ used the word "reckless" in his opinion, he, in fact, applied a knowing and intentional standard. Moreover, the District Court also stated that even if the ALJ had applied a recklessness standard to the 1989 definition of misconduct, such a standard would have been consistent with ORI's precedent. The District Court stated that it "must defer to [the ALJ] if that interpretation of the regulation is reasonable." The District Court also found Dr. Brodie's argument concerning lack of notice of the applicable standard of care to be unpersuasive. In addition, Dr. Brodie unsuccessfully argued that the ALJ erred in determining Dr. Brodie's "present responsibility" when he recommended a seven-year debarment. On all counts, the District Court found that Dr. Brodie failed to demonstrate that the ALJ's conclusions were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.

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complete fact-finding) may never reveal the full facts, unless a journal is willing to add further statements to a matter they had considered closed. And, even when all agree, a retraction may never be published because of other factors, such as an editor's decision, a journal ceasing to exist, or the falsified data appearing in a "non-retractable" publication, such as certain review articles or "supplements" devoted to special topics. Thus, those flawed papers remain in circulation.

This short review illustrates the nature of the problem of correcting literature directly affected by research misconduct. Fortunately, a little-known but accessible means exists for the public correction of the literature via PubMed searches. Also important, this method is independent of the constraints facing journals in these matters.

The Fate of Papers in Misconduct Findings

The current status of publications which were associated with the "case summaries" that were listed on the ORI website in mid-February 2011 was surveyed. ORI's case summaries closely reiterate the text of *Federal Register* Notices (FRNs) and are posted on the ORI website for as long as the administrative actions are active.[1] The results of this limited survey are shown in Table 1.

Results: Twenty-four of the 42 ORI case summaries with active sanctions in February 2011 also involved findings about publications.

TABLE 1: The Status of 88 Publications Cited in *Federal Register* Notices Involving Falsifications (Cases with Active Administrative Actions, February 2011)

- 65 Retractions, Corrections, or Comments in PubMed
  - 57 Full or Partial Retractions (24 postdate the FRN)
  - 8 Errata or Comments (6 predate the FRN)
- 21 Lack Correction or Editorial Comment (or not found)
- 2 "Identified for retraction" by the Journal (but not acted upon)

Those 24 cases included 88[2] individual publications that contained falsified data.[3] Sixty-five papers showed corrections, either through *errata*, corrections, or retractions. Fifty-seven of those showed full or partial retractions, 24 of which were deferred until the publication of the FRN. Evidently, a significant number of either institutions or journal editors relied on U.S. Public Health Service (PHS) findings in reaching their decision.

The remaining eight papers showed *errata* or comments, six of which *predated* the PHS finding. One was for a paper subsequently proven to involve falsification of nine figures; another involved major fabrication of data; and a third reported results for studies subsequently found to have not been conducted.

In 21 of the 88 publications (in some cases involving a paper with multiple falsified figures), there had been no apparent correction of the literature at the time of this survey. Two FRNs listed papers as "partial retractions," and in two others, the journal described the papers in 2008 as "identified for retraction." Yet, by the date of this survey (19 months after the PHS finding), none was found.

Observations: Several factors impact these results. Eight articles could not be found and one journal had ceased to exist. Some journals may insist that all coauthors sign a retraction, an expectation that may not be realistic. Journals also may choose to publish retractions signed by the institutional official or, while a case was active, publish an "expression of editorial concern." Authorship can differ on the retraction, so the original coauthorship is not a foolproof search strategy for finding a specific retraction. Retractions that are not published on a "numbered page" may not be indexed in PubMed. In the past, some editors also might have had policies against retracting review articles, supplements, and proceedings of special topic areas.

The very existence of a retraction is idiosyncratic. ORI and institutions can only make recommendations and requests. However, whether or not a paper is retracted, and how much scientific detail is provided, is ultimately a decision reserved for and implemented by the journals. Recommended guidelines for retractions are available,[4] yet their implementation varies.

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Further Correcting *(from page 5)*

Equally important, when a correction in any form does appear, it should be sufficiently informative to meet the needs of the readership. Yet the text of the retractions, corrections, or *errata* associated with falsified paper rarely explicates the details on which components of a study are false, and/or why.[5]

More Information through PubMed: "Comments" Linking to the NIH Guide for Grants and Contracts

Irrespective of the decisions affecting journal corrections, in PHS misconduct cases, another mechanism exists to inform the research community through its normal and routine use of PubMed to search the literature. When the FRN indicates that the paper was either retracted, or recommended for correction or retraction as a result of a misconduct investigation, a "Comment" will be attached by the National Library of Medicine (NLM), a component of the National Institutes of Health (NIH), to any such paper that is indexed in PubMed, as shown in Fig. 1.[6]

ORI's findings also provide the interested scholar with a direct and simple means to learn more about the details of the experiment, as long as they were specified in the original FRN.[7] Thus, more can be learned about the problematic research from a PubMed search of the literature, regardless of whether a retraction was ever published. Few are aware this information is available; because the full sequence for its retrieval may not be obvious, the steps are illustrated in Figs. 1-3.

All research misconduct findings published in the *Federal Register* are listed in the NIH Guide for Grants and Contracts. When a publication is recommended for retraction in the FRN, NLM attaches a comment about that fact under the title (or abstract if present) in the Abstract display results of a PubMed search, "Comment in: NIH Guide Grants Contracts" (Fig. 1).

Selection of that link next takes the reader to a citation for the NIH Guide for Grants and Contracts specifying in bold print "Findings of Misconduct in Science" (Fig 2).

Selection of either the "LinkOut – more resources" citation or the "LinkOut to related resource" icon from this display (see Fig. 2) will then take the user to the full text of the FRN, as shown next in Fig. 3.

Discussion: Experienced PubMed users may recall that the "Comment" line used to be more prominently displayed directly above the abstract in the PubMed search results. It has now been moved to a less prominent position below the abstract, but it is still available.

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FIGURE 1: Results of a PubMed search for a non-retracted paper that was cited in an FRN for Research Misconduct. This "boxed" annotation indicates the addition of a "Comment" line that is not usually present.

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Because "Comments" are an uncommon feature in the results of a PubMed search, the informed PubMed user will immediately be alerted to the fact that more information is available about an article of specific interest. The FRN may inform the interested scholar about which figures or data were found to have been falsified, perhaps how they were falsified and, by inference, which components of the study are presumed to be correct.

A PubMed link to the FRN is not a timely way to learn more details about the research, because it does not occur until and unless there is a PHS finding. However, it does provide the interested researcher with important information long after knowledge about the case may have been forgotten. Moreover, as this survey reveals, this information might otherwise not be available, and it is provided seamlessly during the course of routine scholarship.

In closing, it is worth noting that ambiguity exists in the fate and wording of retractions even for error or for scientific mistake alone (where the time to retract is increasing).[8] The present observations of the fate of publications from a limited sample of ORI cases suggests that comparable levels of ambiguity exist for papers with significant proven falsification that lead to findings of research misconduct. PubMed "Comments" that link to the NIH Guide for Grants and Contracts, and thus to the FRN, may help partially address this uncertainty.[9]

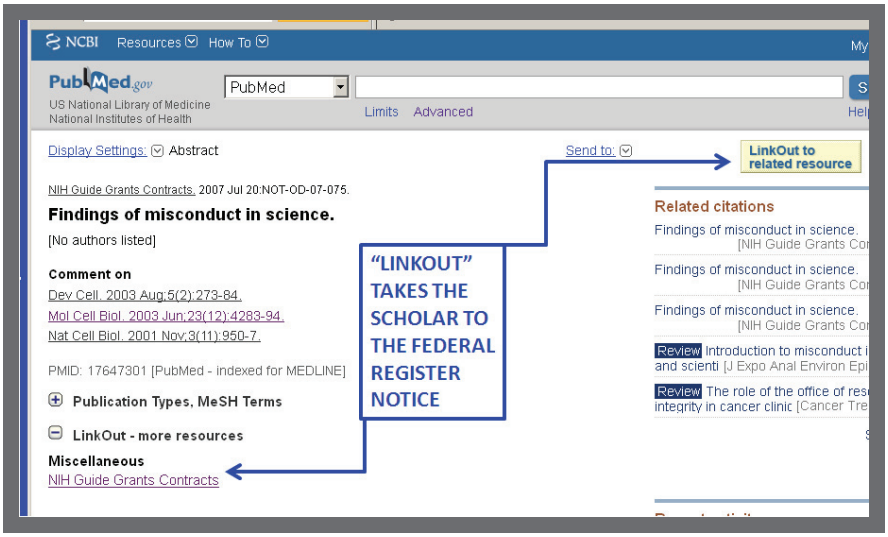
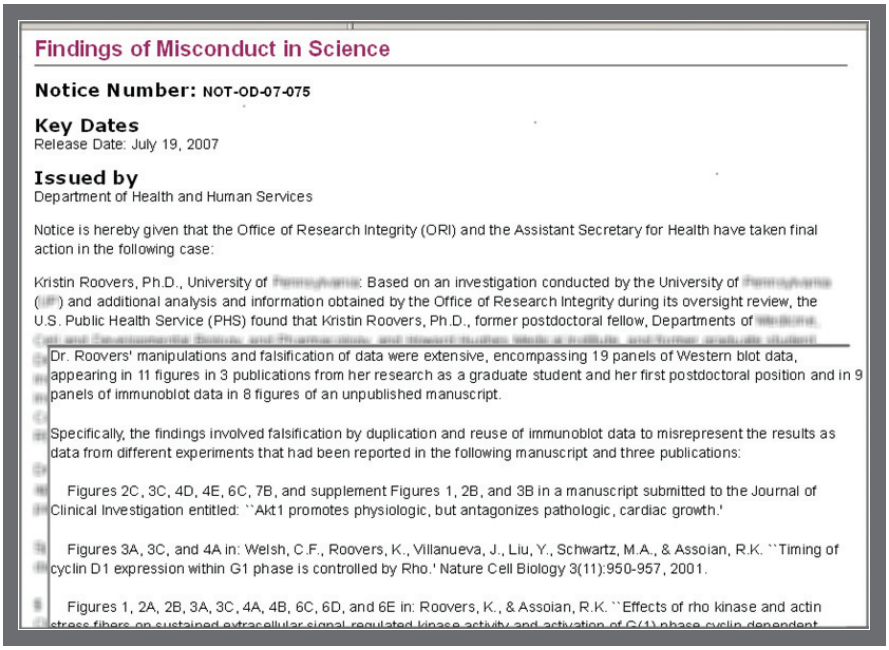


FIGURE 2: Citation for the NIH Guide for Grants and Contracts. This "boxed" annotation points to links to the FRN.


Findings of Misconduct in Science

Notice Number: NOT-OD-07-075

Key Dates
Release Date: July 19, 2007

Issued by
Department of Health and Human Services

Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Kristin Roovers, Ph.D., University of [redacted]: Based on an investigation conducted by the University of [redacted] and additional analysis and information obtained by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Kristin Roovers, Ph.D., former postdoctoral fellow, Departments of [redacted]

Dr. Roovers' manipulations and falsification of data were extensive, encompassing 19 panels of Western blot data, appearing in 11 figures in 3 publications from her research as a graduate student and her first postdoctoral position and in 9 panels of immunoblot data in 8 figures of an unpublished manuscript.

Specifically, the findings involved falsification by duplication and reuse of immunoblot data to misrepresent the results as data from different experiments that had been reported in the following manuscript and three publications:

Figures 2C, 3C, 4D, 4E, 6C, 7B, and supplement Figures 1, 2B, and 3B in a manuscript submitted to the Journal of Clinical Investigation entitled: ``Akt1 promotes physiologic, but antagonizes pathologic, cardiac growth.'

Figures 3A, 3C, and 4A in: Welsh, C.F., Roovers, K., Villanueva, J., Liu, Y., Schwartz, M.A., & Assoian, R.K. ``Timing of cyclin D1 expression within G1 phase is controlled by Rho.' Nature Cell Biology 3(11):950-957, 2001.

Figures 1, 2A, 2B, 3A, 3C, 4A, 4B, 6C, 6D, and 6E in: Roovers, K., & Assoian, R.K. ``Effects of rho kinase and actin stress fibers on sustained extracellular signal-regulated kinase activity and activation of G(1) phase cyclin-dependent

FIGURE 3: My composite overlay of the text, which appears later in the same FRN, giving details about specific figures involved in the research misconduct finding, as seen in the inset.

References and Notes

1. Although removed from the website after expiration of the administrative actions, the content of older cases remains publicly accessible in the archives of the *ORI Newsletter* (published at the time of the finding). See also *http://ori.dhhs.gov/publications/newsletters.shtml*
2. There were actually 95 listings, but seven papers were common to two Respondents.
3. Forty-three of those papers were associated with just four Respondents, with 16 being the most publications associated with one case.

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Case Summaries

Sheng Wang, Ph.D.
Boston University School of Medicine Cancer Research Center

Based on the Respondent's acceptance of ORI's research misconduct findings, ORI found that Dr. Sheng Wang, who has been an Assistant Professor, Department of Medicine, Boston University School of Medicine Cancer Research Center (BUSM), engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants R01 CA102940 and R01 CA101992.

ORI found that the Respondent engaged in research misconduct by fabricating data that were included in two (2) published papers:

1. Zhang, B., Faller, D.V., Wang, S. "HIC1 regulates tumor cell responses to endocrine therapies." *Mol. Endocrinol.* 23(12):2075-85, 2009; and

2. Zhang, B., Chambers, K.J., Leprince, D., Faller, D.V., Wang, S. "Requirement for chromatin-remodeling complex in novel tumor suppressor HIC1-mediated transcriptional repression and growth control." *Oncogene* 28(5):651-61, 2009.

Specifically, ORI found that Respondent:

- fabricated RT-PCR and ChIP experiments represented in Figures 1b, 2b, 3a,b, 4b,c, 6a,b, 7c in *Mol. Endocrinol.* 23(12):2075-85, 2009; RT-PCR and/or ChIP experiments were included in six (6) of seven (7) figures in this publication; and
- fabricated RT-PCR and ChIP experiments represented in Figures 2a,b, 3a,b, 4a,c, 5a,b, 6b,c, 8a,b in *Oncogene* 28(5):651-61, 2009; RT-PCR and/or ChIP experiments were included in six (6) of eight (8) figures in this publication.

Respondent has entered into a Voluntary Exclusion Agreement (Agreement). Respondent and the U.S. Public Health Service (PHS) want to conclude this matter without further expenditure of time or other resources. Respondent accepts ORI's findings of research misconduct as set forth above but neither admits nor denies

Further Correcting *(from page 7)*

4. See sections 3.5 to 3.5.6, "Correcting the Literature," in *CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2009 Update*. Available at *http://www.CouncilScienceEditors.org*

5. It is unfortunate that retractions have taken on a negative connotation, but occasionally, it is still possible to find a "good" retraction, one that reveals lessons about methodology and credits the scientific approach to replicate results.

6. Linking is a direct consequence of the fact that the publication was funded by PHS. PubMed is a database produced by NLM, which, as part of NIH, links to the full text of the NIH Guide for Grants and Contracts. The NIH Guide is required under regulation to report PHS findings of research misconduct.

7. Technically, a Google "Advanced Search" would also reveal the publication's involvement in a research misconduct finding, but that approach requires an affirmative decision by the busy scholar not only to look at, but also to use, the correct search criteria. Also, detailed information about the experiments may be available in the institution's investigation report, a copy that can be released by request to ORI under the Freedom of Information Act (FOIA). However, this process would engender time for review under FOIA regulations.

8. See R. Grant Steen, "Retractions in the scientific literature: Is the incidence of research fraud increasing?" *J Med Ethics.* 2010;37:249-253.

9. Sheldon Kotzin and Lou Knecht of NLM provided helpful comments following their review of the draft manuscript. Gary Lipshultz, DIO, ORI, assisted with the survey.

ORI thanks the following people for contributing articles to the newsletter:

Peter Abbrecht

John Dahlberg

John Krueger

Jo An Rochez

Sandra Titus

Case Summaries *(continued)*

committing research misconduct. The Agreement does not constitute an admission of liability on Respondent's part. Respondent agrees not to appeal the jurisdiction of ORI or request a U.S. Department of Health and Human Services (HHS) administrative hearing to review the findings as set forth in the Agreement.

As a condition of the Agreement, Respondent agrees that the *Mol. Endocrinol.* 23(12):2075-85, 2009, and *Oncogene* 28(5):651-61, 2009, publications be retracted.

By entering into the Agreement, Dr. Wang has voluntarily agreed for a period of two (2) years, beginning on July 18, 2011:

(1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS's Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations"); and

(2) to exclude himself 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.

The above case summary also can be seen on the ORI website (*http://ori.hhs.gov*).

Scott Weber, Ed.D., M.S.N.
University of Pittsburgh

Based on the letters from the Research Integrity Officer at the University of Pittsburgh (UP), ORI's oversight review, and an admission by the Respondent, ORI found that Dr. Scott Weber, former Assistant Professor, Health and Community Systems, School of Nursing, UP, engaged in research misconduct by (1) plagiarizing text and falsifying data from two publications supported by U.S. Public Health Service (PHS) funding (P30 MH60570; HS5 SM52671; PHS employee-generated article) in two unpublished manuscripts, and (2) including significant portions of that plagiarized text in two grant applications to the National Institutes of Health (NIH) (1 L30 NR010444-01; 1 R03 HD062761-01).

ORI found that the Respondent engaged in research misconduct by plagiarizing text, falsifying data and references, and fabricating data from two publications (Mufson, L., Dorta, K.P., Wickramaratne, P., Nomura, Y., Olfson, M., Weissman, M.M. "A randomized effectiveness trial of interpersonal psychotherapy for depressed adolescents." *Arch Gen Psychiatry* 61(6):577-84, 2004 June; hereafter referred to as "Mufson *et al*. 2004"; and Cho, M.J., Mościcki, E.K., Narrow, W.E., Rae, D.S., Locke, B.Z., Regier, D.A. "Concordance between two measures of depression in the Hispanic Health and Nutrition Examination Survey." *Soc Psychiatry Psychiatr Epidemiol.* 28(4):156-63, 1993 August; hereafter referred to as "Cho et al. 1993" supported by PHS in two journal article submissions. Specifically, ORI found that the Respondent plagiarized more than 90 percent of the text from Mufson *et al.* 2004 in a manuscript entitled "A randomized effectiveness trial of psychiatric-mental health nurse practitioner-administered interpersonal psychotherapy for sexual minority adolescents with depression in primary care clinics" and submitted to the *Journal of the American Academy of Nurse Practitioners* (*JAANP MS*). Furthermore, the Respondent plagiarized approximately 66 percent of the text from Cho *et al.* 1993 in a manuscript entitled "Assessing the diagnostic predictive power of a screening tool for depression: Concordance between the CES-D and DIS in the Parent Identity Survey" and submitted to the *Journal of GLBT Family Studies* (*JGMS MS*).

In both manuscripts, the Respondent falsified and fabricated tables

Integrity without knowledge is weak and useless, and knowledge without integrity is dangerous and dreadful.

Samuel Johnson

English author, critic, and lexicographer

(1709 - 1784)

Case Summaries *(continued)*

and figures by using all or nearly all of the data in tables and graphs from the plagiarized articles while altering numbers and changing text to represent data as if from another subject population; he also copied most of the original bibliographic references but falsified 35% of the copied references from *JAANP MS* and 25% of the copied references from *JGMS MS*, by changing volume numbers and/or publication years, apparently to hinder detection of the plagiarism. The data fabrication occurred when the Respondent altered or added values to Table 2 in each manuscript describing the demographic characteristics of the study population that was never studied.

ORI also finds that the Respondent engaged in research misconduct by plagiarizing text from Cho *et al.* 1993 in two NIH grant applications (1 L30 NR010444-01 and 1 R03 HD062761-01) by copying substantial word-for-word portions of the text describing the test instrument to be used in the proposed study without citing the Cho *et al.* 1993 paper.

Dr. Weber has voluntarily agreed for a period of three (3) years, beginning on September 7, 2011:

(1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS's Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations"); and

(2) to exclude himself 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.

The above case summary also can be seen on the ORI website (*http://ori.hhs.gov*).

Integrity can be neither lost nor concealed nor faked nor quenched nor artificially come by nor outlived, nor, I believe, in the long run, denied.

Eudora Welty
American short story writer and novelist
(1909 - 2001)

Shamarendra Sanyal, Ph.D.
Duke University

Based on an inquiry conducted by Duke University (Duke), admissions by the Respondent, and additional analysis conducted by ORI in its oversight review, ORI and Duke found that Dr. Shamarendra Sanyal, former postdoctoral scholar, Duke, engaged in research misconduct by falsifying data in a grant application submitted to the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

Specifically, ORI found that the Respondent falsified Figure 2C of grant application 1 R01 HL107901-01, "Store-operated calcium entry in airway inflammation," by altering the gain settings in the instrument used to measure store-operated current (SOC) densities in a whole cell patch clamp experiment comparing Stim 1+/- mouse airway cells and wild type mouse airway cells. Respondent also falsified the calcium response data in Figure 5A (right panel) of the grant application referenced above by adding ATP as a reagent to the mouse airway epithelial cells to sharpen the results purported to be caused by PGN without disclosing that ATP had been added and without disclosing that ATP was not added to the control sample.

The questioned research was not submitted for publication.

Dr. Sanyal has entered into a Voluntary Settlement Agreement with ORI and Duke, in which he voluntarily agreed to the administrative actions set forth below. The administrative actions are required for two (2) years beginning on the date of Dr. Sanyal's employment in a research position in which he receives or applies for PHS support on or after the effective date of the Agreement (September 16, 2011); however, if he has not obtained

Case Summaries *(continued)*

employment in a research position in which he receives or applies for PHS support within three (3) years of the effective date of the Agreement, the administrative actions set forth below will no longer apply.

Dr. Sanyal has voluntarily agreed:

(1) to have his research supervised as described below and to notify his employer(s)/institutions(s) of the terms of this supervision; Respondent agrees to ensure that prior to the submission of an application for 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 will submit a plan for supervision of Respondent's duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he will not participate in any PHS-supported research from the effective date of this Agreement until a plan for supervision is submitted to and approved by ORI; Respondent agrees to be responsible for maintaining compliance with the agreed-upon plan for supervision;

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

(3) to exclude himself 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.

The above case summary also can be seen on the ORI website (*http://ori.hhs.gov*).

Nicola Solomon, Ph.D.
University of Michigan Medical School

Based on an investigation conducted by the University of Michigan Medical School (UMMS) and a preliminary analysis conducted by ORI, ORI found that Dr. Nicola Solomon, former postdoctoral scholar, Department of Human Genetics, UMMS, engaged in research misconduct in research supported by National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grants R37 HD030428 and R01 HD034283.

Specifically, the Respondent did not perform DNA sequencing on 202 cDNA clones of homeobox genes to confirm their identity and integrity. Through multiple revisions of the manuscript, the Respondent did not discuss this with the corresponding author or question and correct the corresponding author's addition of text indicating that the clones had been fully sequenced and were full length or longer (as indicated in Table 3) when compared to NCBI Mus musculus Unigene. This text supported the use of the Cap-Trapper technique to produce full-length clones for the discovery of new genes without polymerase chain reaction (PCR).

Both the Respondent and the U.S. Public Health Service (PHS) are desirous of concluding this matter without further expenditure of time and other resources and have entered into a Voluntary Settlement Agreement to resolve this matter. This settlement is not an admission of liability on the part of the Respondent.

Respondent and ORI agreed to settle this matter as follows:

(1) Respondent agreed that for a period of two (2) years beginning

Our character...is an omen of our destiny, and the more integrity we have and keep, the simpler and nobler that destiny is likely to be.

George Santayana
Spanish American Philosopher, essayist, poet, and novelist
(1863 - 1952)

Case Summaries *(continued)*

on September 16, 2011, prior to the submission of an application for PHS support for a research project on which her participation is proposed in a research capacity, and prior to her participation in this capacity on PHS-supported research, Respondent shall ensure that a plan for supervising her duties is submitted to ORI for approval; the supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that she shall not participate as a researcher 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; and

(2) Respondent agreed to exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant, for a period of two (2) years, beginning on September 16, 2011.

The above case summary also can be seen on the ORI website (*http://ori.hhs.gov*).

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