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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.

IN THIS ISSUE

RIO Boot Camps: History and Future Plans

David E. Wright, Ph.D., ORI

The Research Integrity Officer (RIO) Boot Camps are part of a major Office of Research Integrity (ORI) initiative to support and to professionalize the role of the RIO. Back in the late 1980s when the misconduct regulation was new, inexperienced RIOs and their institutions sometimes mishandled cases that subsequently ended up in the press and in court. These were painful and expensive episodes for everyone involved.

Over the next 15 years or so, ORI and the first generation of RIOs reached a set of mutual understandings about better approaches to handle cases. The consensus of best practices for RIOs to use in handling allegations is now incorporated into the RIO Boot Camp curriculum. It is a three-day intensive training program for RIOs and their institutional legal counsel.

ORI initiated the Boot Camp program in 2006 and held the first Boot Camp in May 2007. The project started in response to requests from RIOs for training and support, in developing techniques and best practices to handle allegations of misconduct in research, staying current with regulations, and building

(See Boot Camps, page 5)

A Major Misconduct Case: How Computer Forensics Saved the Day

John Dahlberg, Ph.D., ORI

On June 29, 2012, the *Federal Register* published a notice finding that Dr. Mona Thiruchelvam, formerly an Assistant Professor in the Department of Environment and Occupational Health Science Institute (EOHSI), at the University of Medicine and Dentistry of New Jersey (UMDNJ), admitted to committing research misconduct and will have a seven-year period of exclusion from eligibility to apply for or be supported by funds from the Federal Government. This notice marked the end of a lengthy investigative process that was made more difficult by multiple attempts by Dr. Thiruchelvam to mislead and obstruct the efforts of UMDNJ to resolve the multiple allegations of falsification and fabrication of data that were lodged against her.

This article describes those obstructive efforts and how they were overcome to allow UMDNJ and the Office of Research Integrity (ORI) to reach appropriate findings.

(See Misconduct, page 6)

RIOs' Conversations Prepare Whistleblowers

Sandra Titus, Ph.D., ORI, and David Wright, Ph.D., ORI

In a study, "Preparing Whistleblowers for Reporting Research Misconduct" (reported in *Accountability in Research* at *http://dx.doi.org/10.1080/08989621.2012.718683*), the authors, A. Bonito, S. Titus, A. Greene, J. Amoozegar, C. Eicheldinger, and D. Wright, examine four areas of possible conversation that Research Integrity Officers (RIOs) have with whistleblowers. The 77 RIOs were selected because they handled an actual investigation within the prior five years. Specifically, the RIOs were interviewed to learn whether they discussed (1) information on the allegation review process, (2) anonymity and confidentiality, (3) institutional responsibility to protect the whistleblower, and (4) potential adverse experiences. The authors of the study believe that having substantive conversations may help the complainant be less stressed and better prepared. In other fields, professionals spend time in advance with people to prepare them to know how to handle a new situation. For example, sports trainers prepare athletes before a contest, surgeons prepare patients for surgery, and educational programs prepare people to handle the stress of a new school or a new culture. RIOs who discussed more of the areas from categories 1 through 4 in greater depth were more likely to use a checklist or a standard operating procedure, usually had talked with the Office of Research Integrity (ORI) about a hypothetical case, or attended a RIO Boot Camp.

A template could be developed from the detailed list of areas that different RIOs discussed with the interviewers. Not all RIOs discussed every area. Although the regulations do not prescribe that a RIO needs to prepare a complainant, they do require that the institution make all efforts to encourage the submission of allegations and to protect those who submit them against harm and retaliation. Thus, we believe it is important to address and describe many components of the process in order to demonstrate how the institution will strive to protect the whistleblower and allow the individual time to consider issues before making a decision.

SAVE THE DATE: April 3-5, 2013

"ORI AT 20: Reassessing Research Integrity"

A LEADERSHIP CONFERENCE

Sponsored by:
ORI and Johns Hopkins University

Royal Sonesta Harbor Court Hotel
Inner Harbor, Baltimore, MD

Objectives:

1) To examine the history and accomplishments of the first 20 years of handling research misconduct and promoting research integrity, and

2) To evaluate the effectiveness of responsible conduct of research (RCR) efforts, and

3) To enhance leadership and the development of new strategies to promote RCR effective programs.

Time Line of Important Developments in Clinical Trials and FDA's New Role

Sandra Titus, Ph.D., ORI

Just over 10 years ago, it was very difficult to find information on active clinical trials until they were reported in a publication. Now there are five large registries worldwide that provide information on clinical trials. Based on data in the National Institute of Medicine's Clinical Trials Registry (CTR) and database, approximately 21,000 studies are currently registered. Most studies are conducted in non-U.S. sites (49%). An additional 7% are recruited everywhere, whereas 45% are recruited only in the United States. The following is a time line summary of some of the key changes that led to the newly announced U.S. Food and Drug Administration's (FDA's) role with the CTR and database.

1997: The CTR and database were established by the National Institutes of Health (NIH) and maintained by the National Library of Medicine. It is a registry in which all U.S. clinical trials, both publically and privately funded, must be reported.

Researchers who conduct clinical trials were expected to report their research proposals before beginning their studies, as well as report updates and study findings. The CTR and database were established so that the research community could build on knowledge gained from clinical trials.

The registry has multiple purposes for different groups. It can be useful to prospective participants, the public, editors, funders, and institutional review board (IRB) members in understanding a clinical study. It is accessible to everyone through the web site located at *http://clinicaltrials.gov/ct2/about-site*. Fundamentally, the CTR creates an extensive formatted public record of the basic study and findings.

The database generated from the study data also has multiple uses. Scientists, editors, and funders all use the database for different purposes. Adverse events and safety issues can be compared and lead to the development of future research. The results database provides a rich source of information that other researchers can analyze.

2005: Upon awareness by editors that trials were not being uniformly registered, the International Committee of Medical Journal Editors (ICMJE) required registration as a precondition for publishing the trial's findings in member journals. The ICMJE also recognizes four other registries.

2009: A key study was reported by Boutron and colleagues on a random sample of clinical trials. They wanted to compare the primary outcomes of the study proposed against the outcome measures that were reported. In their review of 323 clinical trial articles that reported the findings, they found that nearly 28% of the trials were unregistered. "Among the trials adequately registered, 31 percent (46 of 147) showed some evidence of discrepancies between the outcomes planned in the registry and the outcomes published. The influence of these discrepancies could be assessed in only half of the papers and in these statistically significant results were favored in 82.6 percent (19 of 23)." Hence, researchers published findings that appeared to be inappropriate and biased.

2012 (September 5): Expanded authority for enforcement was delegated to FDA to monitor all clinical trials supported by the Public Health Service (PHS). The notice was published in the *Federal Register* at: *https://s3.amazonaws.com/public-inspection.federalregister.gov/2012-23598.pdf*

The U.S. Department of Health and Human Services' Secretary Kathleen Sebelius delegated to the Commissioner of the Food and Drug Administration the following authority:

Section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii))—To determine that any clinical trial information was not submitted as required under 42 U.S.C. 282(j) or was submitted but is false or misleading in any particular and to notify the responsible party and give such party an opportunity to remedy non-compliance by submitting required revised clinical trial information not later than 30 days after such notification.

References

1. Mathieu, S., Boutron, I., Moher, D., Altman, D. G., & Ravaud, P. (2009). Comparison of registered and published primary outcomes in randomized controlled trials. *Journal of the American Medical Association*, *302*(9), 977–984.

2. Clinical Trials.gov *(http://clinicaltrials.gov/ct2/about-site)*.

NAS Focuses on Next Research Integrity Book

The National Academy of Science (NAS) is revising the 1992 book, *Responsible Science: Ensuring the Integrity of the Research Process*. The Committee on Integrity of the Scientific Record convened a meeting on March 19, 2012, to explore the views of diverse experts regarding current issues that impact research integrity. At this meeting, committee members heard from invited representatives of government agencies including the U.S. Departments of Energy and Health and Human Services, and the U.S. Geological Survey. The Association of American Universities and the Association of American Medical Colleges also presented. The new book will be released in 2013.

The Committee on Integrity of the Scientific Record is charged with addressing the following questions:

- What is the state of current knowledge about modern research practices for a range of disciplines, including trends and practices that could affect the integrity of research? What is the impact of modern technology such as image enhancement, the Internet, and varying data storage systems?
- What are the effects of changing trends such as the dynamics of the research enterprise, globalization, the treatment of intellectual property, the handling of materials and specimens, university oversight and the institutional review board (IRB), and the demands that are created by government regulation?
- What are the advantages and disadvantages of enhanced educational efforts and explicit guidelines for researchers and research institutions? Can the research community itself define and strengthen basic standards for scientists and their institutions? How is this effort impacting collaboration among researchers, in the United States and internationally?
- What roles are appropriate for government agencies, research institutions and universities, and journals in promoting responsible research practices? What can be learned from institutional and journal experiences with current procedures for handling allegations of misconduct in science?
- What should the definition of research misconduct include? Should it include only the criteria of "falsification, fabrication and plagiarism" or should it be broadened to include elements of questionable research practices and research impropriety?
- Should existing unwritten practices be expressed as principles to guide the responsible conduct of research (RCR)? The committee is encouraged to prepare model guidelines and other materials if it deems that such materials would be useful.

The committee members and more information on future open meetings may be found at *http://www8nationalacademies.org/cp/meetingview.aspx?MeetingID=5929&MeetingNo=1*

I cannot find language of sufficient energy to convey my sense of the sacredness of private integrity.

Ralph Waldo Emerson
(1803-1882)

DEI Director John Galland Retires from Government Service

Dr. John Galland retired in September, as the Director of the Division of Education and Integrity (DEI). Dr. Galland joined ORI in the spring of 2009, bringing a unique approach to research education. During his tenure at ORI, he was involved with multiple efforts to promote the responsible conduct of research and prevent research misconduct. Before joining ORI, he directed the University of California-Davis' Laboratory Management Institute, which incorporated an innovative method for training scientists to be able to successfully administer a lab. ORI wishes Dr. Galland well in his future endeavors.

Boot Camps *(from page 1)*

a community of RIOs to provide mutual advice and support. Except for the Boot Camps, new RIOs do not typically benefit from any initial or in-service training from their own institutions or from national organizations for handling their responsibilities.

The RIO Boot Camps bring together veteran RIOs, ORI scientist-investigators, and federal legal counsel to provide training on all critical aspects of a RIO's responsibilities including the following: interviewing respondents and complainants, sequestering data, analyzing forensic data and documents, handling complex allegations that involve more than one research regulation, training inquiry/investigation panels, handling alleged retaliation, handling corrections to the literature and retractions after a misconduct case, and negotiating the regulatory matrix within research institutions and with federal oversight agencies.

To date, ORI has provided 10 Boot Camps. Each of the following universities hosted one Boot Camp: the University of Michigan, Johns Hopkins University, the Poynter Center for the Study of Ethics and American Institutions-Indiana University, the University of Washington, Tulane University, the University of Oregon, the Harvard University Medical School, and the University of California-San Francisco. Northwestern University hosted two Boot Camps.

The RIO Boot Camp project has proven to be popular with RIOs and their legal counsel. An evaluation of the program, entitled "RIO Boot Camps Serve to Support and Professionalize the Role of Research Integrity Officers," was published in the December 2011 *ORI Newsletter*, and may be found at *http://www.ori.hhs.gov/images/ddblock/dec_vol20_no1.pdf*

So that participating RIOs will have ample opportunity to get to know each other and to discuss issues of particular concern to them, ORI limits the Boot Camps to 25 participants by invitation only. Currently, the waiting list has more than 100 RIOs who wish to attend. Additional Boot Camps will be provided in the coming months to reduce this backlog of requests. If you would like to participate, please submit a request to *AskORI@hhs.gov* and provide your title and complete contact information.

ORI will inaugurate a new RIO Boot Camp on advanced topics in the spring of 2013. This Boot Camp will be for those RIOs and counsel who have previously attended a standard RIO Boot Camp. The goals of the new Boot Camp will include: (1) helping RIOs and their counsel prepare for especially difficult cases, (2) helping institutions make sustainable findings when the evidence warrants it, (3) helping RIOs better understand the capabilities of advanced forensic tools and techniques, and (4) building the foundation for future RIO leadership roles that will contribute to and eventually replace the Boot Camp effort with a supportive professional organization for RIOs. An important feature of this Advanced Topics Boot Camp will be the analysis of difficult cases (e.g., requiring an inordinately long time, involving extensive litigation, dealing with breaches of confidentiality and/or retaliation, and determining factors that led to the inability to make sustainable findings) to determine what went wrong and when and how problems might have been prevented. Participating veteran RIOs will handle much of the teaching at the Advanced Topics Boot Camp. There is already an extensive waiting list for the Advanced Topics Boot Camp. ORI will try to offer at least one, perhaps two, of these per year until the backlog is reduced.

Winning is nice if you don't lose your integrity in the process.

Arnold Horshack

NSF's RCR Education Web Site Goes Live

A new Responsible Conduct of Research (RCR) repository web site, designed by the University of Illinois and funded by the National Science Foundation (NSF), recently went live. The repository is known as the Ethics Collaborative Online Resource Environment (CORE). This site may be found at *http://nationalethicscenter.org*. The library encourages educators to share their RCR teaching materials.

Misconduct *(from page 1)*

Research Area

For about a decade, Dr. Thiruchelvam's research focused on the possible effects of environmental insults on the development of Parkinson's disease (PD). She and her colleagues developed an animal model of PD by treating mice with the herbicide paraquat and the fungicide maneb.[1-3]

Both compounds, which are known to be highly toxic, are used by farmers around the world to control weeds and diseases. Partly on the basis of her research showing that exposure to paraquat can lead to PD-like symptoms in the mouse model, the European Union had banned the use of paraquat. However, this model has proven to be controversial.[4]

One of the techniques Dr. Thiruchelvam employed is called stereology. This technique involves the identification and quantification of particular groups of neurons, in a region of the brain called the substantia nigra pars compacta. In brief, sections of mouse brains are treated so that specific types of cells, such as neurons, can be identified in a microscope. A special type of microscope and computer software are then used to automatically count the labeled cells in a sufficient number of sections, to allow the software to accurately determine the number of positive cells in the entire relevant regions of each brain. This procedure is time consuming. It also requires expensive equipment, special software, and appropriate expertise and is often carried out in a core facility within an institution.

Allegations and Counter-Allegations

The allegations of misconduct originally arose because shortly after arriving at UMDNJ, Dr. Thiruchelvam stopped relying on the stereology core facility that was available to her. Yet she still published several papers reporting stereology results. Allegations were made that she must have fabricated her results in a number of published papers, specifically in a manuscript submitted for publication, in a poster presentation, and in grant applications to the National Institutes of Health. When she was made aware of the initial allegations, Dr. Thiruchelvam declared that she had properly conducted the analyses of the mouse brains and also raised counter-allegations against the complainant. (These allegations were proven to be untrue.) The inquiry process initially established Dr. Thiruchelvam's innocence, since she claimed that her stereology data had been provided by an acquaintance from another research institute. The inquiry committee interviewed this individual, using an email address and telephone number provided by Dr. Thiruchelvam; the individual affirmed for the committee that she had generated stereology data for Dr. Thiruchelvam.

Further Efforts to Obstruct the Inquiry and Investigation

During ORI's review, the Division of Investigative Oversight (DIO) staff telephoned the Research Integrity Officer (RIO) at the acquaintance's institution. It was quickly established that Dr. Thiruchelvam had not provided correct contact information on the identified acquaintance, but instead had a personal friend make false claims on her behalf, to mislead the committee. This effort turned out to be one of several by Dr. Thiruchelvam to deceive, delay, or misdirect the inquiry and investigation committees.

Other notable efforts during the investigation included the following: Dr. Thiruchelvam provided a letter, dated December 3, 2009, to UMDNJ from her physician stating that she had been diagnosed with a serious disease and was undergoing treatment. Careful examination of the letter proved it was a hoax. The unsigned letter was on letterhead identifying it as being from a medical practice in Rochester, New York. Notably, the practice's telephone number showed a 716 area code; upon checking area codes for Rochester, UMDNJ officials learned that area codes had been changed, in 2001 in Rochester, to a 585 area code. In addition, when UMDNJ officials contacted the physician's office, they were told that the letter had not been written by any of their physicians.

Corrupted Computer Files

Dr. Thiruchelvam provided the committee 293 files that she claimed to be the raw data generated by the stereology software. They were arranged in folders consistent with the various grant applications and publications in which she had reported stereology data. The file names and creation dates were consistent

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Misconduct *(from page 6)*

with the times the papers and grant applications were submitted. However, every one of the files was corrupted and could not be read by the proprietary software that is used in stereology.

Thus, despite their concerns about Dr. Thiruchelvam's credibility, and the inability to establish that her stereology data were accurately reported, the committee members were unable to make findings on six of the seven issues that they reviewed during the investigation.

DIO's Oversight Review

DIO reviewed the entire record of the case after receiving the final investigation report from UMDNJ. A preliminary analysis suggested that DIO might concur with the investigation committee that a finding of research misconduct, on only one relatively insignificant issue, could be recommended on the basis that the stereology files were unreadable and that they appeared to have been generated at relevant times for the paper and grant application submissions.

Before concluding its review, DIO carried out an enhanced forensic examination of the corrupted files as follows:

- DIO used a forensic software program to generate hash values for 264 files that had unique file names (29 files were duplicates supposedly obtained from the collaborator). DIO determined that 152, or 58%, fell into 40 groups ranging in size from 2 to 18 files with identical content (matching hash values). This indicated that, despite their unique names and time date stamps, the file contents were identical.
- This result was inconsistent with the possibility that a virus was somehow responsible for corrupting the files. Instead, it suggested that great care had been taken to use a few possible authentic stereology files and rename duplicates. It also suggested that a deliberate effort had been made to corrupt the files so that they could not be read by the software.

  DIO investigators analyzed the Microsoft Excel files containing the actual cell numbers counted for the analysis of each mouse. The cell numbers were found in the multiple folders containing the corrupted stereology files. DIO staff thought that if the stereology had not been done, the numbers might have been fabricated. An analysis of the numbers using DigiProbe developed for DIO by James Mosimann,[5] was used to test non-leading right-most digits for uniformity.[6] The analyses revealed that the digits were highly non-uniform, consistent with the hypothesis that they were fabricated, whereas digits from uncontested stereology data were uniformly distributed.
- DIO asked the company that wrote the original software to produce and analyze the stereology results, and to examine a subset of 10 random files. The company's analysis led to the conclusion that each file was from a common source. They wrote:

  "Each file has a series of times starting at 1:10 p.m. August 28, 2002, with the final probe done at 2:15 p.m. the same day" and "It is impossible to see a series of files that all contain probe runs having the same set of times unless they are copied from a single file, so our assumption based on this data is that all these files **were derived from a common source file** (emphasis added)."

With this information, DIO concluded, based on the high degree of file duplication and the use of a single file to generate the 10 files selected at random (that dated back to a time prior to Dr. Thiruchelvam's moving to UMDNJ), that all of the files had been intentionally corrupted. This manipulation had been done by resetting the time and date of her computer so the folders would appear that she had conducted the stereology experiments at times appropriate for their publication and inclusion in grant applications.

Closure

ORI provided the new forensic evidence to officials at UMDNJ to seek their concurrence on the additional findings. The investigation committee reviewed them carefully and concurred with ORI. The university transmitted the new results to Dr. Thiruchelvam for comment; it was important to provide her an opportunity to rebut the additional findings that is required by 42 C.F.R. Part 93. She did not respond.

ORI's findings, which were identical to the contents of the published

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Case Summaries

Mona Thiruchelvam, Ph.D.
University of Medicine and Dentistry of New Jersey

Based on the report of an investigation conducted by the University of Medicine and Dentistry of New Jersey (UMDNJ) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Mona Thiruchelvam, former Assistant Professor, Department of Environment and Occupational Health Science Institute (EOHSI), UMDNJ, engaged in research misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grants P30 ES05022, P30 ES01247, and R01 ES10791 and the intramural program at the National Institute on Drug Abuse (NIDA), NIH.

ORI found that the Respondent engaged in research misconduct by falsifying and fabricating cell count data that she claimed to have obtained through stereological methods in order to falsely report the effects of combined exposure of the pesticides paraquat and maneb on dopaminergic neuronal death and a neuroprotective role for estrogen in a murine model of Parkinson's disease. The Respondent provided to the institution corrupted data files as the data for stereological cell counts of nigrostriatal neurons in brains of several mice and rats by copying a single data file from a previous experiment and renaming the copies to fit the description of 13 new experiments composed of 293 data files when stereological data collection was never performed for the questioned research.

The fabricated data, falsified methodology, and false claims based on fabricated and falsified data were reported in two NIEHS, NIH, grant applications, two publications, a poster, and a manuscript in preparation:

- R01 ES016277, "Development Pesticide Exposure: The Parkinson's Disease Phenotype" (Dr. Mona J. Thiruchelvam Principal Investigator [P.I.]), submitted 1/26/2007 and funded.

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Federal Register notice, were sent to Dr. Thiruchelvam. After a short time, Dr. Thiruchelvam voluntarily agreed to a seven-year period of voluntary exclusion from receiving government funds. She also agreed to request that two of her papers (*Environmental Health Perspectives*, 113(6):708-715, 2005, and *Journal of Biological Chemistry*, 280(23):22530-22539, 2005) be considered for retraction by the editors of the journals.[7,8]

References

1. McCormack, A. L., Thiruchelvam, M., Manning-Bog, A. B., Thiffault, C., Langston, J. W., Cory-Slechta, D. A., & Di Monte, D. A. (2002). Environmental risk factors and Parkinson's disease: Selective degeneration of nigral dopaminergic neurons caused by the herbicide paraquat. *Neurobiology of Disease*, 10,119–127.

2. Thiruchelvam, M., Richfield, E. K., Goodman, B. M., Baggs, R. B., Cory-Slechta, D. A. (2002). Developmental exposure to the pesticides paraquat and maneb and the Parkinson's disease phenotype. *Neurotoxicology*, 23, 621–633.

3. Thiruchelvam, M., McCormack, A., Richfield, E. K., Baggs, R. B., Tank, A. W., Di Monte, D. A., & Cory-Slechta, D. A. (2003). Age-related irreversible progressive nigrostriatal dopaminergic neurotoxicity in the paraquat and maneb model of the Parkinson's disease phenotype. *European Journal of Neuroscience*, *18*(3), 589–600.

4. Miller, G. W. (2007). Paraquat: The red herring of Parkinson's disease research. *Toxicological Sciences*, *100*(1), 1–2.

5. Mosimann, J. E., Wiseman, C. V., & Edelman, R. E. (1995). Data fabrication: Can people generate random digits? *Accountability in Research*, 4, 31–55.

6. Mosimann, J. E., Dahlberg, J. E., Davidian, N. M., & Krueger, J. W. (2002). Terminal digits and the examination of questioned data. *Accountability in Research*, 9, 75–92.

7. Rodriguez, V. M., Thiruchelvam, M., & Cory-Slechta, D. A. (2005). Sustained exposure to the widely used herbicide, Atrazine: Altered function and loss of neurons in brain monoamine systems. *Environmental Health Perspectives*, *113*(6), 708–715.

8. Thiruchelvam, M., Prokopenko, O., Cory-Slechta, D. A., Richfield, E. K., Buckley, B., & Mirochnitchenko, O. (2005). Overexpression of superoxide dismutase or glutathione peroxidase protects against the paraquat + maneb-induced Parkinson disease phenotype. *Journal of Biological Chemistry*, *280*(23), 22530–22539.

Case Summaries *(continued)*

- R01 ES015041, "Gender and the Parkinson's Disease Phenotype" (Dr. Mona J. Thiruchelvam, P.I.), submitted 12/19/05.
- Rodriguez, V.M., Thiruchelvam, M., & Cory-Slechta, D.A. "Sustained Exposure to the Widely Used Herbicide, Atrazine: Altered Function and Loss of Neurons in Brain Monamine Systems." *Environ Health Perspect*. 113(6):708-715, 2005 ("*EHP* paper").
- Thiruchelvam, M., Prokopenko, O., Cory-Slechta, D.A., Richfield, E.K., Buckley, B., & Mirochnitchenko, O. "Overexpression of Superoxide Dismutase or Glutathione Peroxidase Protects against the Paraquat + Maneb-induced Parkinson Disease Phenotype." *J. Biol. Chem*. 280(23):22530-22539, 2005 ("*JBC* paper").
- Harvey, K., Victor, A.I., Wang, Y., Kochar, Y., Cory-Slechta, D.A., & Thiruchelvam, M. "Gene Delivery of GDNF Impedes Progressive Neurodegeneration in Paraquat and Maneb Exposure Model of Parkinson's Disease." Poster presentation, *Neuroscience* 2006 ("*Neuroscience* poster").
- Thiruchelvam, M., Kochar, Y., Mehta, H., Prokopenko, O., Cory-Slechta, D.A., Richfield, E.K., & Mirochnitchenko, O. "Mechanisms associated with gender difference in the paraquat and maneb animal model of Parkinson's disease, 2006 ("manuscript").

Specifically, ORI finds that the Respondent engaged in research misconduct by knowingly and intentionally:

- falsifying and fabricating summary bar graphs and methodology for stereological cell counts in a murine model of Parkinson's disease, when the stereological counts were never performed
- copying and altering in multiple ways a single stereology ".dat" computer file generated on August 18, 2002, and renaming it to generate 293 data files representing counts for 13 new experiments that were never performed, by altering the files to make them unreadable and claiming that these files were from valid stereological cell count experiments carried out at UMDNJ between 2004 and 2006
- falsifying a bar graph representing brain proteasomal activity, by selectively altering data for relative fluorescent unit (RFU) values to support the hypothesis that development of Parkinson's disease entails proteasomal dysfunction with a higher effect in males compared to females
- by failing to perform stereological cell counts, the following figures of summary bar graphs, reported methodology, and related claims of the Respondent's *JBC* paper, *EHP* paper, a manuscript, a poster, and two grant applications were falsified:

(See Case Summaries, page 10)

REMINDER

2012 Institutional Annual Report of Research Misconduct Activities

will be due
between January 1 and March 31, 2013

In December 2012, ORI will be sending an e-mail reminder (with a password and an IPF number) to officials responsible for submitting the 2012 Annual Report.

In order to assure continuous Public Health Service funding support, the report must be submitted between January 1, 2013-March 1, 2013.

Please be sure your e-mail address is up to date in the Annual Report Assurance System, in order to receive your email reminder.

ORI will automatically acknowledge receipt of your submission. You may obtain further information from Robin Parker at robin.parker@hhs.gov or (240) 453-8400.

Case Summaries *(continued)*

  - Figure 7B and the related text in R01 ES016277-01 and the *Neuroscience* 2006 poster
  - Figure 4 and the related text in R01 ES016277-01
  - Figure 9 and the related text in R01 ES016277-01 and R01 ES015041
  - Figure 3 and the related text in the *JBC* paper
  - Figure 4 and the related text in the *EHP* paper
  - Figure 5 and the related text in a manuscript in preparation

- by falsifying and selectively altering experimental data for relative fluorescent unit values of brain proteasomal activity, the summary bar graph in Figure 6 and the claim that combined exposure of the pesticides causes significant decreases in proteasomal activity with a higher effect in males than in females were falsified in NIH grant application R01 ES016277.

Dr. Thiruchelvam has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of seven (7) years, beginning on June 13, 2012:

(1) to exclude herself 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' 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");

(2) 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; and

(3) to request retraction of the following two papers:

- *Environ Health Perspect*. 113(6):708-715, 2005
- *J. Biol. Chem*. 280(23):22530-22539, 2005.

Sinae Kim, Ph.D.
Emory University

Based on the report of an investigation conducted by Emory University (EU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Sinae Kim, former Postdoctoral Fellow, Department of Medicine, EU, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL079137, R01 HL084471, and R03 HL096325, and National Institute of General Medical Sciences (NIGMS), NIH, grant RC1 GM092035.

ORI found that the Respondent engaged in research misconduct by falsifying data that were included in five (5) manuscripts submitted in 2009 for publication to *Blood*, *Nature*, *Nature Biotechnology*, *Nature Medicine*, and *Science*, one (1) poster presented at the 2009 American Heart Association (AHA) meeting, four (4) laboratory meeting presentations, one (1) image file, three (3) funded NIH grants (RC1 GM092035, R01 HL079137, and R03 HL096325), and five (5) submitted NIH grant applications (RC1 HL100648-01, RC2 HL101600-01, RC4 HL106748-01, R01 HD067130-01, and U01 HL107444-01). The manuscripts submitted in 2009 were not accepted for publication.

Specifically, ORI finds that the Respondent knowingly and intentionally:

1. Falsified three (3) figures for immunocytochemistry and alkaline phosphtase (AP) staining images, karyotyping and real-time reverse transcription polymerase chain reaction (RT-PCR) results by using experimental results from her prior work in Korea with human embryonic stem cells (hESCs) to confirm the generation, differentiation, and verification of human induced pluripotent stem cells (iPSCs). The false data were included in:

   a. Figures 1c and 2i (panels 4 & 13) in the *Nature* 2009, *Science* 2009, and *Nature Biotechnology* 2009 manuscripts and Supplementary Figure 4 in the *Nature* 2009 manuscript

   b. Supplementary Figure 5 in the *Nature Biotechnology* 2009 manuscript

   c. Figures S1B and S1D (panels 4 & 13) in the *Blood* 2009 manuscript

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d. Supplementary Figures 8B and 8D (panels 4 & 13) in the *Nature Medicine* 2009 manuscript

e. Figure 9 in the RC1 GM092035 grant

f. Figure 8 in the R01 HL079137 grant

g. Figure 2 in the RC1 HL100648 grant

h. Figure 8 in the RC2 HL101600 grant

i. Figure 3 in the R01 HD067130 grant

j. Figure 1 in the RC4 HL106748 grant

k. Figures 1C, 1H, and 1I (panel 3) in the R03 HL096325 grant

l. Figure 5 in the U01 HL107444 grant

m. Figures 2C and 3I (panels 4 & 13) in the poster presented at the 2009 AHA meeting

n. the presentations "Figures_Sinae Kim_120808.ppt" and "Figures_Sinae Kim_121508.ppt"

Integrity is telling myself the truth. And honesty is telling the truth to other people.

Spencer Johnson
(1940-)

o. the image file "HiPS_E1_x100.jpg."

2. Falsified one (1) figure for the real-time RT-PCR data for endogenous SOX2 expression in human iPSCs derived from dermal (HiPS-E1) and cardiac (HiPS-E2) fibroblasts and iPSCs generated from peripheral blood mononuclear cells derived from coronary artery disease patients (HiPS-ECP1, HiPS-ECP2, and HiPS-ECP3) by substituting real-time RT-PCR data for endogenous OCT4 expression in the forementioned cell lines.

Specifically, the false data were included in:

a. Figure 2i (panels 2 & 5) in the *Nature* 2009, *Science* 2009, and *Nature Biotechnology* 2009 manuscripts

b. Figure S1D (panels 2 & 5) in the *Blood* 2009 manuscript

c. Supplementary Figure 8D (panels 2 & 5) in the *Nature Medicine* 2009 manuscript

d. Figure 3I (panels 2 & 5) in the poster presented at the 2009 AHA meeting

e. the presentations "Figures_Sinae Kim_120808.ppt" and "Figures_Sinae Kim_121508.ppt."

3. Falsified data in two (2) PowerPoint presentations for RT-PCR data of osteogenic-specific gene expression in bone marrow cells by substituting data for RT-PCR data in primary bone-derived and Saos2-osteosarcoma cells.

4. Falsified one (1) figure for the real-time RT-PCR data of OCT4, SOX2, KLF4, c-MYC, NANOG, hTERT, REX1, and GDF3 fold-change expression levels in H1 hESCs, human cardiac and dermal fibroblasts, HiPS-E1, HiPS-E2, HiPS-ECP1, HiPS-ECP2, and HiPS-ECP3 cell lines by substituting data from various other cell lines that did not exist.

Specifically, the false data were included in:

a. Figures 2a-h in the *Nature* 2009, *Science* 2009, and *Nature Biotechnology* 2009 manuscripts

b. Figure 10 in the RC1 GM092035 grant

c. Figure 9 in the R01 HL079137 grant

d. Figure 5 in the R01 HD067130 grant

e. Figure 3A-H in the poster presented at the AHA meeting

f. the presentations "Figures_Sinae Kim_120808.ppt" and "Figures_Sinae Kim_121508.ppt."

5. Falsified research materials when the Respondent distributed cells to laboratory members that she claimed were chemical/non-viral factor induced-mouse iPSCs and human iPSCs generated from peripheral blood of coronary artery disease patients, when she knew they were of other origin.

Dr. Kim has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on June 5, 2012:

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(1) to exclude herself voluntarily 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' 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 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.

Mepur H. Ravindranath, Ph.D.
John Wayne Cancer Institute

Based on the report of an investigation conducted by the John Wayne Cancer Institute (JWCI) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Mepur H. Ravindranath, former Director of the Laboratory of Glycoimmunotherapy, JWCI, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards R21 CA107316 and R03 CA107831.

ORI found that the Respondent engaged in research misconduct by falsifying results reported for research supported by U.S. Public Health Service (PHS) grants R21 CA107316 and R03 CA107831, in progress reports for those grants and in two publications in scientific journals.

It is expressly understood that by entering into a Voluntary Settlement Agreement (Agreement), Respondent is not admitting to any of the allegations made against him by JWCI and/or ORI, or any of their respective agents, employees, associates, or related persons, including but not limited to the findings made by ORI listed in the Agreement. Respondent agreed to enter into the Agreement and not to contest the findings contained therein solely because contesting the findings would cause Respondent undue financial hardship and stress, and Respondent wished to seek finality.

Specifically:

1. Respondent falsified the number of subjects accrued in the double-blind study reported in the paper Ravindranath, M.H., Muthugounder, S., Presser, N., Ye, X., Brosman, S., & Morton, D.L. "Endogenous immune response to gangliosides in patients with confined prostate cancer." *Int. J. Cancer* 166:368-377, 2005 (subsequently referred to as the "*IJC* paper") and later reviewed in Ravindranath, M.H. Yesowitch, P., Sumobay, C., & Morton, D.L. "Glycoimmunomics of human cancer: Current concepts and future perspectives." *Future Oncology* 3(2):201-214, 2007 (subsequently referred to as the "*Future Oncology* paper"), by reporting data of 7 of 63 patients with serial bleeds taken at different points in time and reporting that the values from the 7 patients were for different patients. This same reporting of data of individual patients with serial bleeds taken at different points in time and reporting that those values were for different patients was presented in the CA107316 and CA107831 final reports.

2. The methodology used for the Tables of ANOVA results comparing Log Titers of IgM antibodies for the different subject groups in the *IJC* and *Future Oncology* papers and the CA107316 and CA107831 final reports is incorrect and false, since the papers and reports fail to state that the results are not for a simple ANOVA but include various degrees of repeated measures on the variables.

3. In Table 1 of the CA107831 Final Report, Respondent reported mean log titer values for GM1b for healthy, BHP, and T3/4 CaP patients. These values exactly matched with values published for a different ganglioside, GM1, for healthy, BHP, and T3/4 CaP patients, earlier in the *IJC* (Table II) and *Future Oncology* publications. The only exception was the log titer value for T1/2 CaP patients for GM1b ($n = 20$), which matched with the earlier published mean log titer value for GT1b (6.22 ± 1.40; $n = 36$). ORI finds the pairwise-difference in the log titer values of GM1b between the T1/2 CaP and healthy patients, claimed to be significant ($p<0.01$), to therefore be incorrect and false. Respondent contends otherwise.

4. Because Respondent included serial bleed values from individual

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patients in Table 1 of the *IJC* paper, the summary data for anti-ganglioside antibody values, and the statistical analyses derived from them in Tables II and III of the *IJC* paper, Tables 1 and 2 of the *Future Oncology* paper, published Tables A and B of the CA107316 final report, and Tables 1 and 2B of the CA107831 final report are incorrect and false. The inclusion of serial bleeds from individual patients in Table 1 of the *IJC* paper and their inappropriate impact on the antibody values reported in Table II of the *IJC* paper were reported in detail by Respondent to the Managing Editor in *IJC* in e-mail communications dated September 24 and 29, 2008.

Dr. Ravindranath has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on July 2, 2012:

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

(2) that 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, that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions is his own or properly cites the source of copied language and ideas; and

(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.

Shane Mayack, Ph.D.
Joslin Diabetes Center

Based on the report of an investigation conducted by the Joslin Diabetes Center (Joslin) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Shane Mayack, former postdoctoral fellow, Department of Developmental and Stem Cell Biology, Joslin, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants T32 DK07260-29 and P30 DK036836 and the 2008 NIH Director's New Innovator Award Program grant DP2 OD004345-01.

ORI found that Respondent engaged in research misconduct involving two (2) published papers:

- Mayack, S.R., Shadrach, J.L., Kim, F.S., & Wagers, A.J. "Systemic signals regulate ageing and rejuvenation of blood stem cell niches." *Nature* 463:495-500, 2010
- Mayack, S.R., & Wagers, A.J. "Osteolineage niche cells initiate hemotopoietic stem cell mobilization." *Blood* 112:519-531, 2008.

As a result of Joslin's investigation, both *Nature* 463:495-500, 2010 (hereafter referred to as the "*Nature* paper") and *Blood* 112:519-531, 2008 (hereafter referred to as the "*Blood* paper") have been retracted by the corresponding author.

Specifically, ORI found that:

Respondent falsely represented von Kossa-stained bone nodule images in two (2) published papers:

a. Figure 2B in the *Blood* paper was copied from an unrelated published experiment in Figure 3, *J Orth Surg Res* 1:7, 2006, and was used to falsely represent Respondent's own experiment for bone nodules formed in cultured osteoblastic niche cells

b. Figure S2c in the *Nature* paper was copied from an online image for an unrelated experiment (at *http://skeletalbiology.uchc.*

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edu/30_ResearchProgram/304_gap/3042_Lineage%20in%20Vitro/3042_01_aCellCult.htm#mCOB) and was used to falsely represent Respondent's own experiment for bone nodules formed in osteoblastic niche cells from young and aged mice.

Respondent falsely represented eight (8) flow cytometry contour plots as different experimental results by using identical plots but with different labels and different numerical percentages. Specifically, the following contour plots in the *Blood* paper, the *Nature* paper, an earlier version of the *Nature* paper submitted to *Science* (hereafter referred to as the "*Science* manuscript"), and a July 2008 PowerPoint presentation were identical but were labeled differently:

a. panels 4 and 2 in Figure 6C, *Blood* paper, and panels 1 and 2, respectively, in supplementary Figure 3b, *Nature* paper

b. panel 3 in Figure 6C, *Blood* paper, and panel 1 in Figure 2, July 2008 PowerPoint presentation

c. panels 1 and 2, Figure 2b, *Science* manuscript, and panels 2 and 3, respectively, in Figure 2, July 2008 PowerPoint presentation

d. panels 2, 3, and 4, supplemental Figure 4A, *Blood* paper, and panels 3, 1, and 2, respectively, in Figure 4B, *Science* manuscript

Both the Respondent and HHS want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement to resolve this matter. Respondent neither admits nor denies ORI's finding of research misconduct. This settlement does not constitute an admission of liability on the part of the Respondent. Dr. Mayack has voluntarily agreed:

(1) if within three (3) years from the effective date of the Agreement, Respondent does receive or apply for U.S. Public Health Service (PHS) support, Respondent agrees to have her research supervised for a period of three (3) years beginning on the date of her employment in a research position in which she receives or applies for PHS support and to notify her employer(s)/institution(s) of the terms of this supervision; Respondent agrees that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) if within three (3) years from the effective date of the Agreement, Respondent does receive or apply for PHS support, Respondent agrees 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 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 for a period of three (3) years, beginning on July 27, 2012.

Marc Hauser, Ph.D.
Harvard University

Based on the report of an investigation conducted by Harvard University (Harvard) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Marc Hauser, former Professor, Department of Psychology, Harvard, engaged in research misconduct in research supported by National Center for Research Resources (NCRR), National Institutes of Health (NIH), grants P51 RR00168-37 and CM-5-P40 RR003640-13, National Institute on Deafness and Other Communication Disorders (NIDCD), NIH, grant 5 R01 DC005863, and National

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Institute of Mental Health (NIMH), NIH, grant 5 F31 MH075298.

ORI found that Respondent engaged in research misconduct as follows:

- Respondent published fabricated data in Figure 2 of the paper Hauser, M.D., Weiss, D., & Marcus, G. "Rule learning by cotton-top tamarins." *Cognition* 86:B15-B22, 2002, which reported data on experiments designed to determine whether tamarin monkeys habituated to a sound pattern consisting of three sequential syllables (for example, AAB) would then distinguish a different sound pattern (i.e., ABB). Figure 2 is a bar graph showing results obtained with 14 monkeys exposed either to the same or different sound patterns than they were habituated to. Because the tamarins were never exposed to the same sound pattern after habituation, half of the data in the graph was fabricated. Figure 2 is also false because the actual height of the bars for the monkeys purportedly receiving the same test pattern that they had been habituated to totaled 16 animals (7.14 subjects as responding and 8.87 subjects as non-responding).

Respondent retracted the paper in 2010 (*Cognition* 117:106).

- In two unpublished experiments designed to test whether or not tamarin monkeys showed a greater response to certain combinations of unsegmented strings of consonants and vowels than others, Respondent falsified the coding of some of the monkeys' responses, making the results statistically significant, when the results coded by others showed them to be non-significant. Respondent acknowledged to his collaborators that he miscoded some of the trials and that the study failed to provide support for the initial hypothesis. This research was never written up for publication.
- In versions of a manuscript entitled "Grammatical Pattern Learning by Human Infants and Monkeys" submitted to *Cognition*, *Science*, and *Nature*, Respondent falsely described the methodology used to code the results for experiments 1 and 3 on "grammar expectancy violations" in tamarin monkeys either by claiming coding was done blindly or by fabricating values for inter-observer reliabilities, when coding was done by only one observer, in both cases leading to a false proportion or number of animals showing a favorable response.
- Specifically, in three different experiments in which tamarin monkeys were exposed first to human voice recordings of artificial sounds that followed grammatical structure and then exposed to stimuli that conformed to or violated that structure, Respondent (1) provided an incorrect description of the coding methodology by claiming in the early versions of the manuscripts that "two blind observers" coded trials and a third coded trials to resolve differences, while all of the coding for one experiment was done just by the Respondent, and (2) in a revised manuscript, while Respondent no longer mentioned "two blinded observers," he claimed that "Inter-observer reliabilities ranged from 0.85 to 0.90," a statement that is false because there was only one observer for one of the experiments.
- Furthermore, in an earlier version of the manuscript, Respondent falsely reported that "16 out of 16 subjects" responded more to the ungrammatical rather than the grammatical stimuli for the predictive language condition, while records showed that one of the sixteen responded more to grammatical than ungrammatical stimuli, and one responded equally to grammatical and ungrammatical.

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Integrity is not a conditional word. It doesn't blow in the wind or change with the weather. It is your inner image of yourself, and if you look in there and see a man who won't cheat, then you know he never will.

John D. MacDonald
(1916-1986)

Case Summaries *(continued)*

Respondent and his collaborators corrected all of these issues, including recoding of the data for some of the experiments prior to the final submission and publication in *Cognition* 2007.

- In the paper Hauser, M.D., Glynn, D., Wood, J. "Rhesus monkeys correctly read the goal-relevant gestures of a human agent." *Proceedings of the Royal Society B* 274:1913-1918, 2007, Respondent falsely reported the results and methodology for one of seven experiments designed to determine whether rhesus monkeys were able to understand communicative gestures performed by a human.
- Specifically, (1) in the "Pointing without food" trial, Respondent reported that 31/40 monkeys approached the target box, while the records showed only 27 approached the target (both results are statistically significant), and (2) there were only 30 videotapes of the "Pointing without food" trials, while Respondent falsely claimed in the paper's Materials and Methods that "each trial was videotaped." Respondent was not responsible for the coding, analyses, or archiving, but takes full responsibility for the falsifications reported in the published paper. Respondent and one of his coauthors replicated these findings with complete data sets and video records and published them in *Proceedings of the Royal Society B* 278(1702):58-159, 2011.
- Respondent accepts responsibility for a false statement in the Methodology section for one experiment reported in the paper Wood, J.N., Glynn, D.D., Phillips, B.C., & Hauser, M.D. "The perception of rational, goal-directed action in nonhuman primates." *Science* 317:1402-1405, 2007. The statement in the paper's supporting online material reads that "All individuals are . . . readily identifiable by natural markings along with chest and leg tattoos and ear notches." In fact, only 50% of the subjects could be identified by this method, thus leading to the possibility of repeated testing of the same animal.
- Respondent and one of his coauthors replicated these findings with complete data sets and video records and published them in *Science* 332:537, 2011 (*www.sciencemag.org/cgi/content/full/317/5843/1402/DC2*—published online 25 April 2011).
- Respondent engaged in research misconduct by providing inconsistent coding of data in his unpublished playback experiment with rhesus monkeys exploring an abstract pattern in the form of AXA by falsely changing the coding results where the prediction was that habituated animals were more likely to respond to an ungrammatical stimulus than a grammatical one. After an initial coding of the data by his research assistant, in which both Respondent and assistant agreed that an incorrect procedure was used, the Respondent recoded the 201 trials and his assistant coded a subset for a reliability check. The Respondent's codes differed from the original in 36 cases, 29 of them in the theoretically predicted direction, thereby producing a statistically significant probability of $p = <0.01$. Respondent subsequently acknowledged to his collaborators that his coding was incorrect and that the study failed to provide support for the initial hypothesis. This research was never written up for publication.

Respondent neither admits nor denies committing research misconduct but accepts ORI has found evidence of research misconduct as set forth above and has entered into a Voluntary Settlement Agreement to resolve this matter. The settlement is not an admission of liability on the part of the Respondent. Dr. Hauser has voluntarily agreed for a period of three (3) years, beginning on August 9, 2012:

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

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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 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, that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions is his own or properly cites the source of copied language and ideas; and

(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.

There is no such thing as a minor lapse of integrity.

Tom Peters
(1942-)

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