DATES: To ensure consideration, comments must be received by August 27, 2012. Comments received after this date will be considered only as time permits.

ADDRESSES: Individuals, groups, and organizations interested in commenting on this topic may submit comments by email to info@bioethics.gov or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues. Telephone: 202–233–3960. Email: *hillary.viers@bioethics.gov.* Additional information may be obtained at *http://www.bioethics.gov.*

SUPPLEMENTARY INFORMATION: On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues (the Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged to identify and promote policies and practices that ensure ethically responsible conduct of scientific research and healthcare delivery. Undertaking these duties, the Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

On January 6, 2012, HHS Secretary Kathleen Sebelius asked the Commission to ''conduct a thorough review of the ethical considerations of conducting clinical trials of medical countermeasures in children,'' including the ethical considerations of conducting a pre- and post-event pediatric study of Anthrax Vaccine Adsorbed (AVA) as a component of post-exposure prophylaxis, in order to address ''how best to obtain clinical data on medical countermeasures in children.'' Accordingly, the Commission is examining ethical issues surrounding the development of medical treatments to keep children safe in the event of a public health emergency. While significant progress has been made in the development of medical countermeasures for adults, the development of similar products for children has lagged, in part because of challenges in conducting safety and immunogenicity studies. In the 2011 report, ''Challenges in the Use of Anthrax Vaccine Adsorbed (AVA) in the Pediatric Population as a Component of Post-Exposure Prophylaxis,'' the National Biodefense Science Board recommended that the Department of Health and Human Services move forward with testing AVA before a public health emergency but only after the ethical considerations are adequately addressed and reviewed.

The Commission is requesting public comment on the ethical issues associated with the development of medical countermeasures for children, including ethical considerations surrounding clinical research with children, ethical considerations surrounding pediatric medical countermeasure research, and ethical considerations surrounding emergency access to and use of medical countermeasures. To this end, the Commission is inviting interested parties to provide input and advice through written comments.

The Commission is particularly interested in policies, practices, research, and perspectives on ethical issues associated with pre- and post-event studies testing the safety, dose, and/or immunogenicity of medical countermeasures for and with children. Among other issues, specifically:

- How to conceptualize and consider risk and societal value when reviewing pediatric clinical research in general and for medical countermeasures in particular;
- the types of information, data, or facts needed to ensure evidence-based decision-making for conducting pediatric medical countermeasure research;
- possible criteria, if any, that might classify proposed studies testing medical countermeasures for pediatric use as minimal risk;
- ethical issues related to access to and allocation of medical countermeasures previously studied within pediatric populations in a public health emergency;
- scientific and public health strategies that could minimize the risk or ethical concerns associated with pediatric medical countermeasure research;
- strategies for communicating risk to prospective participants and their families; and
- the role communities play in the design and support of pediatric research and pediatric medical countermeasure research.

Please address comments by email to info@bioethics.gov, or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: June 15, 2012.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2012–15841 Filed 6–27–12; 8:45 am]

BILLING CODE 4154–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

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.

• 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:

—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 CFR part 376 *et seq*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR 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.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2012–15887 Filed 6–27–12; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Friday, July 13, 2012, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The meeting will be held at the Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850.

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, Coordinator of the Advisory Council, at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850, (301) 427–1456. For press-related information, please contact Alison Hunt at (301) 427–1244.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827–4840, no later than Friday, March 16, 2012. The agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850. Ms. Campbell's phone number is (301) 427–1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality is