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Dated: January 18, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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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:

Rao M. Adibhatla, Ph.D., University of Wisconsin: Based on the report of an investigation conducted by the University of Wisconsin (UW) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Rao M. Adibhatla, Assistant Professor, Department of Neurological Surgery, UW, engaged in research misconduct by falsifying results in two publications supported by National Institute of Neurological Diseases and Stroke (NINDS), National Institutes of Health (NIH), grant R01 NS042008 and in three unfunded applications that Dr. Adibhatla submitted to NINDS, NIH, as R01 NS042008-05, -05A1, and -05A2. The questioned papers are:

1. Adibhatla, R.M., Hatcher, J.F., Larsen E.C. *et al.* "CDP-choline Significantly Restores Phosphatidylcholine Levels by Differentially Affecting Phospholipase A₂ and CTP:Phosphocholine Cytidyltransferase after Stroke." *J. Biol. Chem.* 281:6718-6725, 2006 (hereafter referred to as the "*JBC* paper"), as the sPLA₂-IIA, CCT α , and PLD2 data in Figures 1B, 2A, and 3A, respectively
2. Adibhatla, R.M., & Hatcher, J.F. "Secretory phospholipase A₂ IIA is Up-regulated by TNF- α and IL-1 α / β after Transient Focal Cerebral Ischemia in Rat." *Brain Research* 1134:199-205, 2007 (hereafter referred to as the "*Brain Research* paper"), as the sPLA₂-IIA data in Figures 2A and 2C.

ORI found that Respondent committed research misconduct by falsifying Western blot images as well as quantitative and statistical data obtained from purported scans of the films. The research studied the effect of cerebral ischemia on phospholipid homeostasis in an experimental animal model (SHR rat) of stroke during the course of reperfusion of the ischemic cortex. The falsified Western blot images and derivative quantitative data describe changes in levels of sPLA₂-IIA, CCT α , and of PLD2 during reperfusion in the ischemic cortex.

Specifically, the Respondent:

- Falsified the Western blot data demonstrating sPLA₂ expression in a time course after ischemia in Figure 1B of the *JBC* paper and Figure 2A and 2C of the *Brain Research* paper by rearranging the bands such that the labels do not accurately portray what is in the lanes. He perpetuated the falsification by presenting the quantification of the single falsified Western blot in a bar graph as the average of five (5) replicate Western blots. The result in the paper cannot be substantiated by the actual experiments.

- Falsified the Western blot data demonstrating CCT α expression in a time course assay after ischemia in Figure 2A of the *JBC* paper by rearranging the bands such that the labels do not accurately portray what is in the lanes. He perpetuated the falsification by presenting the quantification of the single falsified Western blot in a bar graph as the average of four (4) replicate Western blots and the six (6) hour time point was further falsified to make the results look better. The result in the paper cannot be substantiated by the actual experiments.

- Falsified the quantification of a Western blot demonstrating PLD2 expression in a time course after ischemia in Figure 3A of the *JBC* paper by claiming a bar graph quantifying a single Western blot is the average of four Western blots.

- Submitted the same falsified Western blot images and bar graph data in three unfunded grant applications: NS042008-05, NS042008-05A1, and NS042008-05A2. Specifically:
 - < the falsified sPLA₂-IIA data were submitted as Figures 3, 8, and 12 in the respective NS042008-05, -05A1, and -05A2 applications
 - < the falsified CCT α data appeared as Figures 10, 15, and 16 in the respective -05, -05A1, and -05A2 applications
 - < The falsified PLD2 bar graph data and associated statistical claims appeared as Figures 8 and 13 in the -05 and -05A1 applications respectively.

Dr. Adibhatla has entered into a Voluntary Exclusion Agreement and has voluntarily agreed:

(1) To exclude himself voluntarily for a period of two (2) years from the effective date of the Agreement 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 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 himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years beginning on December 18, 2012; and

(3) To request retraction of the following papers:

- *J. Biol. Chem.* 281:6718-6725, 2006
- *Brain Research* 1134:199-205, 2007.

FOR FURTHER INFORMATION CONTACT:

Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8200.

David E. Wright,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Organizations To Serve as Non-Voting Liaison Representatives to the Chronic Fatigue Syndrome Advisory Committee (CFSAC)

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

Authority: 42 U.S.C. 217a, section 222 of the Public Health Service (PHS) Act, as amended. The committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Office of the Assistant Secretary for Health (OASH), within the Department of Health and Human Services (HHS), is soliciting nominations from qualified organizations to be considered for non-voting liaison representative positions

on the Chronic Fatigue Syndrome Advisory Committee (CFSAC). CFSAC provides advice and recommendations to the Secretary of HHS, through the Assistant Secretary for Health (ASH), on a broad range of issues and topics related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The issues can include factors affecting access and care for persons with ME/CFS; the science and definition of ME/CFS; and public health, clinical, research, and educational issues related to ME/CFS. These three non-voting liaison representative positions will be occupied by individuals who are selected by their organizations to serve as representatives of organizations concerned with ME/CFS. Organizations will be designated to occupy the positions for a two-year term to commence during the 2013 calendar year. Nominations of qualified organizations are being sought for these three non-voting liaison representative positions. The organizations chosen for representation on CFSAC will be selected by the Designated Federal Officer (DFO) or designee during the 2013 calendar year. Details of nomination requirements are provided below.

DATES: Nominations must be received no later than 5 p.m. EDT on February 22, 2013, at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Nancy C. Lee, M.D., Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201. Nomination materials, including attachments, may be submitted electronically to cfsac@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Nancy C. Lee, M.D., Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201. Inquiries can be sent to cfsac@hhs.gov.

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of HHS, through the ASH, on issues related to ME/CFS. CFSAC advises and makes recommendations on a broad range of topics including: (1) The current state of knowledge and research; the relevant gaps in knowledge and research about the epidemiology, etiologies, biomarkers and risk factors

relating to ME/CFS; and potential opportunities in these areas; (2) impact and implications of current and proposed diagnostic and treatment methods for ME/CFS; (3) development and implementation of programs to inform the public, health care professionals, and the biomedical research communities about ME/CFS advances; and (4) strategies to improve the quality of life of ME/CFS patients. Management and support services for Committee activities are provided by staff from the HHS Office on Women's Health, within the OASH. The CFSAC charter is available at <http://www.hhs.gov/advcomcfs/charter/index.html>.

CFSAC meetings are held not less than two times per year. The CFSAC membership consists of 11 voting members, including the Chair. The voting members are composed of seven biomedical research scientists, and four individuals with expertise in health insurance, health care delivery, private health care services, or representatives of voluntary organizations concerned with the problems of individuals with ME/CFS. CFSAC also includes seven non-voting *ex officio* member representatives from the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, National Institutes of Health, and Social Security Administration.

The CFSAC structure has been expanded to include three non-voting liaison representative positions. Authorization was given for the Committee structure to include the three non-voting liaison representative positions when the charter was renewed on September 5, 2012. These positions will be occupied by individuals who are selected by their organizations to serve as the official representative for organizations that are concerned with ME/CFS. Organizations will occupy these representative positions for a two-year term.

Nominations

The OASH is requesting nominations of organizations to fill three non-voting liaison representative positions for the CFSAC. The represented organizations will be selected by the DFO or designee during the 2013 calendar year.

Selection of organizations that will serve as non-voting liaison representatives will be based on the organization's qualifications to contribute to the accomplishment of the CFSAC mission, as described in the Committee charter. In selecting

organizations to be considered for these positions, the OASH will give close attention to equitable geographic distribution and give priority to U.S.-chartered 501(c)(3) organizations that operate within the United States and have membership with demonstrated expertise in ME/CFS and related research, clinical services, or advocacy and outreach on issues concerning ME/CFS.

The individual designated to serve as the official non-voting liaison representative will perform the associated duties without compensation, and will not receive per diem or reimbursement for travel expenses. The organizations that are selected to be represented will cover expenses for the designated representative to attend, at a minimum, one in-person CFSAC meeting per year during the designated term of appointment.

To qualify for consideration of selection to the Committee, an organization should submit the following items:

(1) A statement of the organization's history, mission, and focus, including information that demonstrates the organization's experience and expertise in ME/CFS and related research, clinical services, or advocacy and outreach on issues of ME/CFS, as well as expert knowledge of the broad issues and topics pertinent to ME/CFS. This information should demonstrate the organization's proven ability to work and communicate with the ME/CFS patient and advocacy community, and other public/private organizations concerned with ME/CFS, including public health agencies at the federal, state, and local levels.

(2) One to three letters of recommendation that clearly state why the organization is qualified to serve on CFSAC in a representative position. These letters should be from individuals who are not part of the organization's leadership.

(3) A statement that the organization is willing to serve as a non-voting liaison representative of the Committee and will cover expenses for an individual representative to attend in-person, at a minimum, one CFSAC meeting per year in Washington, DC during the designated term of appointment.

(4) A current financial disclosure statement (or annual report) demonstrating the organization's ability to cover expenses for an individual to attend, at a minimum, one CFSAC meeting per year in Washington, DC, during the term of appointment.

Submitted nominations must include these critical elements in order for the organization to be considered for one of the non-voting liaison representative positions.

Nomination materials should be typewritten, 12-point type and double-spaced. All nomination materials should be submitted (postmarked or received) by February 22, 2013.

Electronic submissions: Nomination materials, including attachments, may be submitted electronically to cfsac@hhs.gov.

Telephone and facsimile submissions cannot be accepted.

Regular, Express, or Overnight Mail: Written documents may be submitted to the following addressee only: Nancy C. Lee, Designated Federal Officer, CFSAC, Office on Women's Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201.

HHS makes every effort to ensure that the membership of Federal advisory committees is fairly balanced in terms of points of view represented. Every effort is made to ensure that a broad representation of geographic areas, sex, ethnic and minority groups, and people with disabilities are given consideration for membership on Federal advisory committees. Selection of the represented organizations shall be made without discrimination against the composition of an organization's membership on the basis of age, sex, race, ethnicity, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Dated: January 18, 2013.

Nancy C. Lee,

Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0841]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of

Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Management Information System for Comprehensive Cancer Control Programs—Revision (OMB No. 0920-0841, exp. 1/31/2013)—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Through the National Comprehensive Cancer Control Program (NCCCP), CDC currently provides cooperative agreement funding and technical assistance to 65 entities: all 50 states, the District of Columbia, seven tribes/tribal organizations, and seven territories/U.S. Pacific Island jurisdictions. Since January 2010, NCCCP awardees have submitted progress and activity information to CDC twice per year using an electronic information system ("Management Information System for Comprehensive Cancer Control Programs," OMB No. 0920-0841, exp. 1/31/2013). The program director for each awardee is responsible for overseeing activities and submitting the required reports to CDC.

New cooperative agreements were awarded to all NCCCP programs in 2012 ("Cancer Prevention and Control Program for State, Territorial and Tribal Organizations," Funding Opportunity Announcement (FOA) DP12-1205). The new cooperative agreements place increased emphasis on policy and environmental approaches to cancer prevention and control.

CDC seeks OMB approval to continue using MIS-based reporting for the NCCCP awardees. Minor changes to the existing core cancer prevention and control data elements will be implemented to reflect the FOA's new performance requirements.

Thirteen of the 65 NCCCP awardees received additional funding for related but distinct cooperative agreements ("Demonstrating the Capacity of Comprehensive Cancer Control Programs to Implement Policy and Environmental Cancer Control Interventions," FOA DP10-1017). The demonstration program is aimed at accelerating the development of policy and environmental approaches to cancer control for awardees that are poised to move forward rapidly. Demonstration program activities will be aligned with the existing comprehensive cancer control program in a manner that minimizes duplication, capitalizes on

existing activities, and fosters rapid implementation. Similar semi-annual progress reports are required to monitor activities conducted under the demonstration program. A state- or territory-based policy task force coordinator will be responsible for submitting the required reports to CDC.

CDC proposes to use the same MIS-based methodology for all reporting. Due to the distinct objectives, resources, and activities associated with each cooperative agreement, separate reports will be required from the program director and the task force coordinator.

CDC's Revision request utilizes a modified method of estimating respondent burden which distinguishes between (i) the initial burden of populating the MIS, and (ii) routine MIS maintenance and report generation. In the initial OMB approval period (2010-2013), respondent burden was based on a long-term average burden per response.

For the 65 state- and territory-based cancer prevention and control programs, CDC estimates the initial burden of populating the MIS at four hours per response. Some of the information entered into the MIS during the previous cooperative agreement period will be downloaded to minimize respondent burden in the new funding period, but awardees will be responsible for verifying this information and entering new objectives. After completing these steps, the estimated burden for ongoing system maintenance and semi-annual reporting is three hours per response.

For the 13 states and territories that are also participating in the demonstration program, the initial burden of populating the MIS is estimated to be six hours per response. Awardees will be responsible for entering information about the new objectives, staff, and other resources for demonstration program activities. Thereafter, the estimated burden for ongoing system maintenance and semi-annual reporting is estimated at three hours per response.

OMB approval is requested for three years. Information will be reported electronically twice per year. CDC will use the reports to identify training and technical assistance needs, monitor compliance with cooperative agreement requirements, evaluate progress made in achieving program-specific goals, and obtain information needed to respond to inquiries. There are no costs to respondents other than their time. The total estimated annualized burden hours are 586.