

Page 2 – Ms. Sigismondi, Chembio Diagnostic Systems.

Chembio should instruct customers who have remaining DPP Zika IgM Assay System EUA product inventory to work with Chembio to replace the EUA product with the device cleared under K200506. FDA encourages Chembio to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of the EUA revocation and provide access to the device cleared on June 3, 2020, under premarket notification submission K200506.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: July 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020-16014 Filed 7-23-20; 8:45 am]

BILLING CODE 4164-01-C

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Prasadarao Nemani, Ph.D. (also known as Nemani V. Prasadarao) (Respondent), Research Professor of Pediatrics, Division of Infectious Disease, Children's Hospital Los Angeles (CHLA). Dr. Nemani engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants R01 AI040567 and R01 AI049473. The administrative actions, including supervision for a period of four (4)

years, were implemented beginning on July 7, 2020, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case: *Prasadarao Nemani, Ph.D., Children's Hospital Los Angeles*: Based on the report of an investigation conducted by CHLA and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Prasadarao Nemani, Research Professor of Pediatrics, Division of Infectious Disease, CHLA, engaged in research misconduct in research supported by PHS funds, specifically NIAID, NIH, grants R01 AI040567 and R01 AI049473.

ORI found that Respondent engaged in research misconduct by recklessly including falsified and/or fabricated data in the following published paper and grant applications submitted for PHS funds:

- *Infect Immun.* 2009;77:1031-43 (hereafter referred to as "*Infect Immun* 2009"). Retraction in: *Infect Immun.* 2018 May 22;86(6):e00212-18

- R01 AI107015-01 submitted to NIAID, NIH
 - R01 AI125595-01A1 submitted to NIAID, NIH
 - R01 AI125595-01 submitted to NIAID, NIH
 - R01 NS073115-06A1 submitted to the National Institute of Neurological Disorders and Stroke (NINDS), NIH
- Respondent recklessly reported falsified and/or fabricated image data for enterobacterial infection-induced intestinal epithelial cell injury in a neonatal murine model to falsely represent results using images from unrelated experiments in eight (8) figures included in one (1) published paper and four (4) grant applications. Specifically, Respondent falsely reported the following figures:
- Figure 1C in *Infect Immun* 2009
 - Figures 7, 8A, 8B, and 8C in R01 AI107015-01
 - Figure 6C in R01 AI125595-01A1
 - Figure 6C R01 AI125595-01
 - Figure 5B in R01 NS073115-06A1
- Dr. Nemani entered into a Voluntary Settlement Agreement and agreed to the following:
- (1) Respondent agreed to have his research supervised for a period of four (4) years beginning on July 7, 2020. Respondent agreed that prior to the

submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, 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) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of four (4) years from the effective date of the Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals, setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of any PHS grant applications (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application/publication is supported by the research record.

(3) Respondent agreed that for a period of four (4) years beginning on July 7, 2020, any institution employing him shall submit, in conjunction with each application of 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.

(4) If no supervisory plan is provided to ORI, Respondent agreed to provide certification to ORI at the conclusion of the supervision period that he has not

engaged in, applied for, or had his name included on any application, proposal, or other request for PHS funds without prior notification to ORI.

(5) Respondent agreed 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 four (4) years, beginning on July 7, 2020.

Dated: July 20, 2020.

Elisabeth A. Handley,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2020–16034 Filed 7–23–20; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Member Conflict: Molecular & Cellular Neurobiology, August 4, 2020, 1:00 p.m. to 05:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, which was published in the **Federal Register** on July 10, 2020, 85 FR 41607.

This notice is being amended to change the meeting date from August 4, 2020 to August 10, 2020 and meeting time from 1:00 p.m. to 5:00 p.m. to 11:00 a.m. to 5:00 p.m. The meeting is closed to the public.

Dated: July 20, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–16023 Filed 7–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Cardiovascular Sciences.

Date: August 20, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, (301) 435–5575, hamannkj@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 20, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–16020 Filed 7–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; NTU COVID–19.

Date: August 10, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.