

docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: ODAC@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The particular matter for this meeting will be review and discussion of a list of molecular targets for which evidence and/or biologic rationale exist to determine their potential relevance to the growth or progression of one or more pediatric cancers and a list of those targets deemed unlikely to be associated with the growth or progression of pediatric tumors. These lists are expected to fulfill the statutory obligation of the Food and Drug Administration Reauthorization Act (FDARA) and provide some guidance to industry in planning for initial Pediatric Study Plan submissions for new drug and/or biologic products in development for cancer in accordance with the amended provisions of the Pediatric Research Equity Act. The committee will review and discuss considerations other than scientific relevance that FDA will include in decision making with respect to the need and timing of pediatric evaluation of specific new drug and biologic products. The committee will discuss possible criteria and mechanisms for the prioritization by sponsors and the clinical investigator community of select targeted new agents for pediatric evaluation especially in the setting of multiple same in class agents. Preliminary discussion will focus on approaches to coordination and collaboration for pediatric clinical investigations of new agents that might

be pursued to efficiently accommodate international regulatory requirements and global pediatric product development. The open public hearing sessions are: Topic 1: Target List, Topic 2: FDARA Implementation, and Topic 3: Mechanisms to Assure Efficiency and to Enhance Global Coordination Through International Collaboration.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before June 5, 2018, will be provided to the subcommittee. Oral presentations from the public will be scheduled between approximately 10:25 a.m. and 10:45 a.m., 1:40 p.m. and 2 p.m., and 3:40 p.m. and 4:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 25, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 29, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a

disability, please contact Lauren D. Tesh (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-10337 Filed 5-14-18; 8:45 am]

BILLING CODE 4164-01-P

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 on the part of Gareth John, Ph.D., Professor, Department of Neurology, Icahn School of Medicine at Mount Sinai (ISMMS). Dr. John engaged in research misconduct in research supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grants R01 NS056074 and R01 NS062703. The administrative actions, including one (1) year of supervision, were implemented beginning on April 26, 2018, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Wanda K. Jones, Dr.P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, 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:

Gareth John, Ph.D., Icahn School of Medicine at Mount Sinai: Based on Respondent's admission, the report of an inquiry and investigation conducted by ISMMS, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Gareth John, Professor, Department of Neurology, ISMMS, engaged in research misconduct in research supported by NINDS, NIH, grants R01 NS056074 and R01 NS062703.

ORI found that Respondent engaged in research misconduct by knowingly and intentionally falsifying data reported in *Development* 141(12):2414–28, 2014 Jun (hereafter referred to as “*Development* 2014”).

In addition to making an admission, Respondent cooperated fully with ISMMS and ORI and has expressed remorse for his actions.

Specifically, ORI found that Respondent:

- used the p-GSK3 α / β double bands in Figure S3B of *Development* 2014, removed the lower set of bands, reordered the remaining bands and used those bands to represent the actin control in an experiment comparing the impact of Tgfb1 and ActB individually and in combination in primary oligodendrocyte progenitors (OLPs) and the oligodendrocyte-derived Oli-Neu cell line.

- used the densitometry readings from the falsified actin bands in Figure S3B of *Development* 2014 to compare the density of A+T, Tgfb1, ActB, and Veh relative to the false actin signal in Figure S3C–J, creating eight false graphs.

- falsified the bands representing Myelin basic protein (Mbp) in Figure 3C of *Development* 2014 by cutting and pasting the bands onto a blank background and used those false bands to create a graph showing the density of Mbp in the presence and absence of ActB, Tgfb1, and Bmp4.

As a result of this admission, Respondent has notified *Development* that corrections to figures in the paper, but not to the text, including the conclusions in *Development* 2014 are required.

Dr. John entered into a Voluntary Settlement Agreement and voluntarily agreed, beginning on April 26, 2018:

(1) To have his research supervised for a period of one (1) year; Respondent agreed that prior to submission of an application for U.S. Public Health Service (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 for one (1) year, 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 and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) if no supervisory plan is provided to ORI, 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;

(4) 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 one (1) year; and

(5) to follow up with the journal editor regarding his previous request to correct the following paper to ensure that the corrections are made:

- *Development* 141(12):2414–28, 2014 Jun.

Wanda K. Jones,

Interim Director, Office of Research Integrity.

[FR Doc. 2018–10310 Filed 5–14–18; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of Microbiology, Infectious Diseases and AIDS Initial Review Group Microbiology and Infectious Diseases Research Committee.

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: Microbiology, Infectious Diseases and AIDS Initial Review Group Microbiology and Infectious Diseases Research Committee.

Date: June 7–8, 2018.

Time: 9:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3E72A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892934, (240) 669–5023, fdesilva@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 10, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–10316 Filed 5–14–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

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 Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 BTRC Review (2018/10).

Date: July 5–7, 2018.

Time: 6:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Courtyard by Marriott New York Manhattan/Upper ES, 410 East 92nd Street, New York, NY 10128.

Contact Person: Manana Sukhareva, Ph.D., Scientific Review Officer, National Institute