III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm, or http://www.hhs.gov/ohrp/newsroom/index.html, or http://www.regulations.gov.

Dated: October 23, 2015.

Karen B. DeSalvo,

Acting Assistant Secretary for Health. U.S. Department of Health and Human Services.

Dated: October 27, 2015.

Leslie Kux.

Assistant Commissioner for Policy, U.S. Food and Drug Administration.

[FR Doc. 2015-27986 Filed 11-4-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, November 12, 2015, 10:00 a.m. to November 12, 2015, 02:00 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD, 20892 which was published in the **Federal Register** on October 19, 2015, 80 FR 63236.

The meeting notice is amended to change the date of the meeting from November 12, 2015 to November 24, 2015. The meeting is closed to the public.

Dated: October 30, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28230 Filed 11–4–15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Therapeutics To Treat Brain Injury and Neurodegenerative Disease

AGENCY: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7, that the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Astrocyte Pharmaceuticals, Inc., ("Astrocyte"), a company incorporated under the laws of Delaware and having an office in Cambridge, Massachusetts, to practice the following inventions embodied in the following patent applications: US Provisional Patent Appl. No. 60/176,373 entitled, "Methanocarba cycloalkyl nucleoside analogues," filed 14 Jan 2000 [HHS reference E-176-1999/0-US-01]; Intl. Appl. No. PCT/US01/00981, entitled, "Methanocarba cycloalkyl nucleoside analogues," filed 12 Jan 2001 [HHS reference E–176–1999/0–PCT–02]; Australia Patent No. 2001230913, issued 13 Oct 2005 [HHS reference E-176-1999/0-AU-03]; Canada Patent No. 2.397,366, issued 15 Mar 2011 [HHS reference E-176-1999/0-CA-04]; European Patent Appl. No. 01903043.6 entitled, filed 12 Jan 2001 [HHS Ref No E-176-1999/0-EP-05]; US Patent No. 7,087,589, issued 8 Aug 2006 [HHS reference E-176-1999/0-US-06]; US patent No. 7,790,735, issued 8 Aug 2006 [HHS reference E-176-1999/0-US-07]: and Great Britain patent No. 1252160, issued 16 Aug 2006 [HHS reference E-176–1999/0–US–08]. The patent rights in these inventions have been assigned to the United States of America. The territories included in this license may be worldwide. The field of use may be related to "Use of the patent rights in the development and sale of therapeutics for cerebral trauma, stroke, and neurodegenerative disorders."

DATES: Only written comments or applications for a license (or both) which are received by the Technology Advancement Office of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) on or before November 20, 2015 will be considered. **ADDRESSES:** Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Patrick McCue, Ph.D., Senior Licensing and Patenting Manager, Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases, 12A South Drive, Bethesda, MD 20892, Telephone: (301) 435-5560; Email: patrick.mccue@nih.gov. A signed confidentiality non-disclosure agreement will be required to receive copies of any patent applications that have not been published by the United

States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

The technology provides novel nucleoside and nucleotide derivatives that are agonist or antagonists of P1 and P2 receptors and may be useful in the treatment or prevention of various diseases including airway diseases, cancer, cardiac arrhythmias, cardiac ischemia, epilepsy, and Huntington's Disease.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIDDK receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Properly filed competing applications for a license received by the NIDDK in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 30, 2015.

Anna Z. Amar,

Acting Deputy Director, Technology Advancement Office, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2015-28245 Filed 11-4-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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 Cancer Institute Special Emphasis Panel, NCI Provocative Questions—Cancer with an Underlying HIV Infection.

Date: December 9, 2015. Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W514, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Peter J. Wirth, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W514, Rockville, MD 20850, 240–276–6434, pw2q@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, NCI Program Project Meeting I (P01).

Date: January 27–28, 2016. Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 7400
Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Delia Tang, MD, Scientific
Review Officer, Research Programs Review

Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602, Bethesda, MD 20892, 240–276–6456, tangd@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, NCI Program Project Meeting II (P01).

Date: February 2–3, 2016. Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Caterina Bianco, MD, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W610, Bethesda, MD 20892–9750, 240–276–6459, biancoc@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, NCI SPORE Review II.

Date: February 3–4, 2016. Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: David G. Ransom, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W124, Rockville, MD 20850, 240–276–6351, david.ransom@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, NCI SPORE III Review.

Date: February 4–5, 2016. Time: 8:00 a.m. to 5:00 p.m. Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W120, Bethesda, MD 20852, 240–276–6457, mh101v@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: October 30, 2015.

Melanie J. Grav,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28229 Filed 11–4–15; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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; Cancer Health Disparities/Diversity in Basic Cancer Research Special Emphasis Panel.

Date: November 12, 2015. Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Arnold Revzin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7824, Bethesda, MD 20892, (301) 435– 1153, revzina@csr.nih.gov. This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Health Disparities/Diversity in Basic Cancer Research.

Date: November 12–13, 2015. Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Svetlana Kotliarova, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, 301–451–3493, kotliars@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: October 30, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28227 Filed 11–4–15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the Board of Regents of the National Library of Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 materials, and personal information concerning individuals associated with the grant