

600.90 have been approved under OMB control number 0910-0308.

### III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: August 25, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-20635 Filed 8-28-14; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Service Administration

#### Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

*Name:* Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD).

*Dates and Times:* September 15, 2014, 9:00 a.m.–2:00 p.m. (EST).

*Place:* Webinar and Conference Call Format.

*Status:* The meeting will be open to the public.

*Purpose:* The ACTPCMD provides advice and recommendations on a broad range of issues related to grant programs authorized by sections 222 and 749 of the Public Health Service Act, as amended by section 5103(d) and re-

designated by section 5303 of the Patient Protection and Affordable Care Act of 2010.

*Agenda:* This webinar meeting will begin with opening remarks from Health Resources and Service Administration (HRSA) senior officials and include a final discussion and vote on the committee's 11th Report to Congress. Additional agenda items include: review of a letter of support for the Teaching Health Center Graduate Medical Education program, a brief program update by HRSA staff, and discussion on a topic for the committee's next report.

The agenda will be available 2 days prior to the meeting on the HRSA Web site (<http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html>). Agenda items are subject to change as priorities dictate.

*Public Comment:* An opportunity will be provided for public comment at the end of the meeting, or written comments to the members may be sent, not later than five days prior to the meeting date, to Shane Rogers at [srogers@hrsa.gov](mailto:srogers@hrsa.gov). As this meeting will be conducted via webinar format, a Question and Answer Pod will also be available for public comment as well.

#### SUPPLEMENTARY INFORMATION:

Information on accessing the webinar will be available via the following Web site not later than two days prior to the meeting date: <http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Shane Rogers, Designated Federal Official, ACTPCMD, Bureau of Health Workforce, Health Resources and Services Administration, Room 12C-06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, call 301-443-5260, or email [srogers@hrsa.gov](mailto:srogers@hrsa.gov).

Dated: August 22, 2014.

**Jackie Painter,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2014-20599 Filed 8-28-14; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Service Administration

#### Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

*Name:* Council on Graduate Medical Education (COGME).

*Dates and Times:* September 12, 2014, 9:00 a.m.–3:00 p.m. (EST).

*Place:* Webinar and Conference Call Format.

*Status:* The meeting will be open to the public.

*Purpose:* The COGME provides advice and recommendations to the Secretary of the Department of Health and Human Services and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs.

*Agenda:* This webinar meeting will begin with opening remarks from Health Resources and Service Administration (HRSA) senior officials and include a vote on the Council's next Vice Chair. The meeting will also include discussion on the Council's 22nd Report to Congress as well as a brief update by the Designated Federal Official on the Council's current status.

The agenda will be available 2 days prior to the meeting on the HRSA Web site (<http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html>). Agenda items are subject to change as priorities dictate.

*Public Comment:* An opportunity will be provided for public comment at the end of the meeting, or written comments to the members may be sent, no later than 5 days prior to the meeting date, to Shane Rogers at [srogers@hrsa.gov](mailto:srogers@hrsa.gov). As this meeting will be conducted via webinar format, a Question and Answer Pod will also be available for public comment as well.

#### SUPPLEMENTARY INFORMATION:

Information on accessing the webinar will be available via the following Web site no later than 2 days prior to the meeting date: <http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Shane Rogers, Designated Federal Official, COGME, Bureau of Health Workforce, Health Resources and Services Administration, Room 12C-06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, call 301-443-5260, or email [srogers@hrsa.gov](mailto:srogers@hrsa.gov).

Dated: August 22, 2014.

**Jackie Painter,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2014-20598 Filed 8-28-14; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive Start-up Option License: Use of Oligodeoxynucleotide as Neuroprotectants in Cerebral and Other Ischemic Injury

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive start-up option license to practice the inventions embodied in: (E-147-1999/0 & 1) US provisional patent application No. 60/128/898 filed 4/12/1999, and PCT application No. PCT/US00/09839 filed 4/12/2000, and U.S. patent No. 6,977,245 filed 02/06/2002 issued 12/20/2005, and U.S. patent No. 7,960,356 filed 05/17/2005 and issued 06/14/2011, and EP1176966 granted 4/3/2013, each entitled "Oligodeoxynucleotide and Its Use to Induce an Immune Response"; and (E-036-2005/0) US provisional patent application No. 60/713,547 filed August 31, 2005, and PCT application No. PCT/US2006/033774 filed August 28, 2006, and US patent 7,892,569 filed 8/31/2005 issued 2/22/2011, and Canada application number 2620582 filed 2/28/08, and Australia patent 2006284889 filed 8/28/2006 issued 12/1/11, and Japan patent 5481068 filed 8/28/2006 issued 2/21/2014, each entitled "Method of Altering an Immune Response Induced by CpG Oligodeoxynucleotides"; and (E-214-2001/0) US provisional patent application No. 60/312,190 filed August 14, 2001, and PCT application No. PCT/US202/025732, and US patent 7,354,909 filed February 2, 2004 issued April 8, 2008, and US patent 7,959,934 filed March 28, 2008 issued June 14, 2011, each entitled "Method for Rapid Generation of Mature Dendritic Cells" by Klinman et al. (FDA), to Neuralexo, LLC, having a place of business at 17367 Canal Circle, Lake Oswego, Oregon 97035.

The United States of America is an assignee to the patent rights of these inventions.

The prospective exclusive start-up option licensed territory may be worldwide, and the field of use may be limited to: preventative treatment for ischemic injury in organs.

**DATES:** Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before September 15, 2014 will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: [fennet@mail.nih.gov](mailto:fennet@mail.nih.gov); Telephone: 424-297-0336; Facsimile: 301-402-0220.

#### SUPPLEMENTARY INFORMATION:

This invention relates to compositions and methods of use of oligodeoxynucleotides (ODNs) expressing CpG motifs to induce immune responses. These ODN motifs trigger immune system responses which may mediate inflammatory responses to tissue injury, such as those responses following ischemic damage to the central nervous system. Structural differences between various ODNs may stimulate distinct cell populations, allowing selective targeting of immune responses for therapeutic purposes. Non-human primate and animal models using specific ODNs for pharmacological preconditioning have shown that ODNs may act therapeutically as neuroprotectants from ischemic damage. These TLR ligands as may be useful therapeutically as neuroprotectants in ischemic injury.

The prospective exclusive start-up option 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 start-up option license may be granted unless the NIH 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 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up option 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: August 25, 2014.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 2014-20548 Filed 8-28-14; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meeting

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 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 Institute on Aging Special Emphasis Panel ADRC Review Meeting.

*Date:* October 14-15, 2014.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC-9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7707, [elainelewis@nia.nih.gov](mailto:elainelewis@nia.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: August 25, 2014.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014-20552 Filed 8-28-14; 8:45 am]

**BILLING CODE 4140-01-P**