

technology providers in specific areas to collaborate on computational science, describe best practices in challenging areas, and propose methods for addressing knowledge gaps. A description of the project groups and planned activities can be found at <http://www.phuse.eu/css.aspx>.

**II. Registration and Accommodations**

*A. Registration*

All registrants (with the exception of a limited number of speakers and/or organizers who will have a complimentary registration) will pay a fee for this meeting to help defray the costs of facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete the registration form online at (<https://www.phuse.eu/PhUSE-CSS-2016-Registration.aspx>). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). The costs of registration for the different categories of attendees are as follows:

| Attendee category  | Fee (\$) |
|--|----------|
| Government/nonprofit/academia .....  | 300      |
| Industry Organizing Committee & PhUSE Board of Directors (password required) .....       | 350      |
| Poster presenter (includes the printing of the poster by PhUSE, password required) ..... | 375      |
| Industry .....   | 750      |
| Single-day .....   | 650      |
| Registering after the conference begins .....  | 1250     |

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to: [office@phuse.eu](mailto:office@phuse.eu).

*B. Accommodations*

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the DoubleTree by Hilton Silver Spring Hotel are eligible for a reduced rate of \$189 not including applicable taxes. Those making reservations online should use the following link to receive the reduced rate: [http://doubletree.hilton.com/en/dt/groups/personalized/D/DCASSDT-PHU-20160312/index.jhtml?WT.mc\\_id=POG](http://doubletree.hilton.com/en/dt/groups/personalized/D/DCASSDT-PHU-20160312/index.jhtml?WT.mc_id=POG).

If you need special accommodations because of disability, please contact Chris Decker (see **FOR FURTHER INFORMATION CONTACT**) at least 14 days in advance.

**III. Transcripts**

We expect that transcripts will be available approximately 30 days after the meeting. A transcript can be obtained either in hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301-827-9267.

Dated: February 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-02877 Filed 2-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-0247]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On October 21, 2015, the Agency submitted a proposed collection of information entitled “Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

number. OMB has now approved the information collection and has assigned OMB control number 0910-0429. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of General Medical Sciences; 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:* NIGMS Initial Review Group, Training and Workforce Development Subcommittee—D.

*Date:* March 11, 2016.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

*Contact Person:* Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, Bethesda, MD 20892, 301-594-2771, [johnsonrh@nigms.nih.gov](mailto:johnsonrh@nigms.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: February 8, 2016.

**Melanie J. Gray,**

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

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; 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 of General Medical Sciences Special Emphasis Panel; Review of R13 Research Grants.

*Date:* March 16, 2016.

*Time:* 12:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, Room 3AN.12N, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Nina Sidorova, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.22, Bethesda, MD 20892-6200, 301-594-3663, [sidorova@nigms.nih.gov](mailto:sidorova@nigms.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical

Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: February 8, 2016.

**Melanie J. Gray,**

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

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; 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 Institute of General Medical Sciences Special Emphasis Panel; Renewal of Centers of Biomedical Research Excellence (COBRE) (P20).

*Date:* March 4, 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, Bethesda, MD 20852.

*Contact Person:* Shinako Takada, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12M, Bethesda, MD 20892, 301-402-9448 [shinako.takada@nih.gov](mailto:shinako.takada@nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Review of Clinical Trials.

*Date:* March 8, 2016.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific

Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12P, Bethesda, MD 20892, 301-594-3907, [pikbr@mail.nih.gov](mailto:pikbr@mail.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Renewal of Centers of Biomedical Research Excellence (COBRE) (P20).

*Date:* March 9, 2016.

*Time:* 8:30 a.m. to 4:00 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:* Nina Sidorova, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12K, Bethesda, MD 20892, 301-402-2783, [sidorova@nigms.nih.gov](mailto:sidorova@nigms.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel.

*Date:* April 4, 2016.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12P, Bethesda, MD 20892, 301-594-3907, [pikbr@mail.nih.gov](mailto:pikbr@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: February 8, 2016.

**Melanie J. Gray,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; 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.,