

Because there still is a need for HHS to clarify its interpretation of how the orphan drug exclusion in the 340B Program should be implemented to be consistent with section 340B(e) of the PHSA, HHS is making available an interpretive rule on this topic. In short, this interpretive rule clarifies that HHS interprets section 340B(e) of the PHSA as excluding drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug was designated under section 526 of the FD&C Act. This section of the PHSA does not exclude drugs that are transferred, prescribed, sold, or otherwise used for conditions or diseases other than for which the drug was designated under section 526 of the FD&C Act.

II. Electronic Access

Persons with access to the Internet may obtain the document at www.hrsa.gov/opa/programrequirements/interpretiverule/.

Dated: July 16, 2014.

Mary K. Wakefield,

Administrator, Health Resources and Services Administration.

Dated: July 18, 2014.

Sylvia M. Burwell,
Secretary.

[FR Doc. 2014–17409 Filed 7–21–14; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health 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: Environmental Health Sciences Review Committee.

Date: August 14–15, 2014.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Imperial Hotel & Convention Center, 4700 Emperor Boulevard, Durham, NC 27703.

Contact Person: Linda K Bass, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 17, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–17262 Filed 7–22–14; 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 (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: Center for Scientific Review Special Emphasis Panel Member Conflict: Cardiovascular and Respiratory Sciences.

Date: August 21, 2014.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Margaret Chandler, Ph.D., Scientific Review Officer, Center

for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301) 435–1743, margaret.chandler@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 17, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–17259 Filed 7–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

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 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 Deafness and Other Communication Disorders Advisory Council.

Date: September 12, 2014

Closed: 8:30 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Room 6C6, 31 Center Drive, Bethesda, MD 20892.

Open: 10:00 a.m. to 2:00 p.m.

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: National Institutes of Health, Building 31, Room 6C6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, Ph.D., Director, Division of Extramural Activities NIDCD, NIH, Room 8345, MSC 9670, 6001 Executive Blvd., Bethesda, MD 20892–9670, 301–496–8693, jordanc@nidcd.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.nidcd.nih.gov/about/Pages/Advisory-Groups-and-Review-Committees.aspx>, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: July 17, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–17261 Filed 7–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2); 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer.

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

Name of Committee: National Cancer Institute Special Emphasis Panel NCI Experimental Therapeutics Program (Cycle 17 NEXT).

Date: August 22, 2014.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 6C06, Bethesda, MD 20892.

Contact Person: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, MD 20892, (301) 496–4291, mroczkoskib@mail.nih.gov.

Joseph Tomaszewski, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, MD 20892, (301) 496–6711, tomaszej@mail.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: July 17, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–17260 Filed 7–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for “Stories of Basic Science to Medical Advances” Challenge

Authority: 15 U.S.C. 3719.

SUMMARY: The National Institute of General Medical Sciences (NIGMS), one of the components of the National Institutes of Health (NIH), announces a challenge titled “Stories of Basic Science to Medical Advances.” This Challenge aims to track medical advances stemming from NIGMS-supported basic science.

DATES: Submission Period: July 21, 2014–October 20, 2014.

Judging Period: October 21, 2014–November 20, 2014.

Winners announced: 14 days after judging is complete.

FOR FURTHER INFORMATION CONTACT: Darren Sledjeski, Ph.D. 301–594–0943, nigms_challenges@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The mission of NIGMS is to support basic, non-disease-targeted research that increases understanding of life processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS-funded researchers seek to answer important scientific questions to increase our knowledge about the mechanisms and pathways involved in diseases and develop new tools and techniques that have medical applications. NIGMS’ strategic plan states that one of its goals is to “advance awareness and understanding of the basic biomedical research enterprise, including its value, requirements, and potential impact.” Accomplishing this goal, however, can be difficult because the path between basic discoveries and their applications is often long, and the connections can be hard to track.

In addition to tracking the medical advances stemming from NIGMS-supported science, the Challenge is also intended to attract more interest and attention to the basic science research funded by NIGMS; stimulate innovation by acknowledging the key role that NIGMS funded research plays in laying the foundation for advances in disease diagnosis, treatment and prevention; and advance the statutory purpose of NIGMS to “conduct and support research and health information dissemination with respect to general or basic medical sciences and related natural and behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.” 42 U.S.C. 285k.

Subject of Challenge: NIH seeks the public’s help in capturing NIGMS’ progress toward its strategic goal to “advance awareness and understanding of the basic biomedical research enterprise, including its value, requirements, and potential impact.” The goal of the Challenge is to identify past advances that are serving (or have served) to improve human health and well-being but not ongoing studies that may, in the future, have a major impact. NIGMS will use these examples to help inform the historical context of scientific breakthroughs and NIGMS’