

safety. These sections describe essential considerations intended to provide high-level guidance on the implementation of these approaches in pediatric drug development and have been revised based on comments received from global stakeholders.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "E11(R1) Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Electronic Access

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

Dated: April 4, 2018.

**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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. Attendance is limited by the 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 open session will also be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>).

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 Advisory General Medical Sciences Council.

*Date:* May 24–25, 2018.

*Closed:* May 24, 2018, 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

*Open:* May 25, 2018, 8:30 a.m. to 12:00 p.m.

*Agenda:* For the discussion of program policies and issues; opening remarks; report of the Director, NIGMS; and other business of the Council.

*Place:* National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Ann A. Hagan, Ph.D., Associate Director for Extramural Activities, NIGMS, NIH, DHHS, 45 Center Drive, Room 2AN24H, MSC 6200, Bethesda, MD 20892–6200, (301) 594–4499, [hagana@nigms.nih.gov](mailto:hagana@nigms.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.nigms.nih.gov/About/Council>, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 5, 2018.

**Melanie J. Pantoja,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Frederick National Laboratory Advisory Committee to the National Cancer Institute.

The meeting will be open to the public, 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 also be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>).

*Name of Committee:* Frederick National Laboratory Advisory Committee to the National Cancer Institute.

*Date:* May 8, 2018.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* Ongoing and new activities at the Frederick National Laboratory for Cancer Research.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Conference Room TE406, Rockville, MD 20850.

*Contact Person:* Caron A. Lyman, Ph.D., Executive Secretary, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 7W-126, Bethesda, MD 20892, 240-276-6348, [lymanca@mail.nih.gov](mailto:lymanca@mail.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, NCI Shady Grove has instituted stringent procedures for entrance into the NCI Shady Grove building. 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://deainfo.nci.nih.gov/advisory/fac/fac.htm>, where an agenda and any additional information for the meeting will be posted when available.

(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)