The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored by FDA and the University of Maryland Center for Excellence in Regulatory Science and Innovation Industrial Consortia Members, and Federal Government employees. There is a $50.00 registration fee for all other participants. Early registration is recommended because seating is limited. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Leslie Wheelock (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

In many instances, these resources allow for the timely evaluation of drug-related adverse events since data on healthcare utilized by a large number of individuals are readily available. However, because these data are typically collected for administrative purposes, information on important health factors necessary to evaluate drug-outcome relationship may be
absent or incomplete in these data sources. Examples include tobacco/smoking use and history, alcohol consumption, weight and height, patient and family medical history, or use of over-the-counter medications. Incomplete capture or the absence of this information can result in biased or uncertain estimates for the drug-outcome relationship of interest leading to inadequate evaluation of the safety profile of prescription drug products. Webcast: Please be advised that as soon as possible after a Webcast of the public workshop is available, it will be accessible at: http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm429136.htm.

Dated: April 13, 2015.
Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute on Drug Abuse; 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 Advisory Council on Drug Abuse.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: May 5–6, 2015.
Closed: May 5, 2015, 1:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.
Open: May 6, 2015, 8:30 a.m. to 2:00 p.m.
Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative, and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.
Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, NSC, Room 5274, MSC 9591, Rockville, MD 20892, 301–443–6487, sweiss@nida.nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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.

Information is also available on the Institute’s/Center’s home page: www.drugabuse.gov/NACDA/NACDAHome.html where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 13, 2015.
Carolyn Baum,
Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of Nursing Research; 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 Advisory Council for Nursing Research.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Nursing Research.

Date: May 19–20, 2015.
Open: May 19, 2015, 1:00 p.m. to 5:00 p.m.
Agenda: Discussion of Program Policies and Issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Room 6, Bethesda, MD 20892.
Closed: May 20, 2015, 9:00 a.m. to 1:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Room 6, Bethesda, MD 20892.
Contact Person: Ann R. Knebel, DNSC, RN, FAAN, Deputy Director, National Institute of Nursing Research, National Institutes of Health, 31 Center Drive, Building 31, Room 5B05, Bethesda, MD 20892, 301–496–8230, knebelar@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, NIH has instituted stringent procedures for entrance onto the NIH campus. A list of 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: www.nih.gov/ninr/a_advisory.html, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)