data to support analytical methodologies. The recommendations in this guidance apply to new drug applications, abbreviated new drug applications, biologics license applications, and supplements to these applications. The principles in this guidance also apply to Type II drug master files. This guidance does not address investigational new drug application (IND) methods validation specifically, but the principles being discussed may be helpful to sponsors preparing INDs.

This guidance complements the International Conference on Harmonisation guidance ''Q2(R1) Validation of Analytical Procedures: Text and Methodology.''

In the **Federal Register** of February 19, 2014 (79 FR 9467), this guidance was published as a draft guidance. We have carefully reviewed and considered the comments that were received on the draft guidance and have made changes for clarification.

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 analytical procedures and methods validation. 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.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 211, 21 CFR part 314, and 21 CFR part 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0338.

III. Comments

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 document at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: July 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18270 Filed 7–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 80 FR 37639–37640 dated July 1, 2015).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (RM). Specifically, this notice: (1) Establishes the Office of Policy and Planning (RMA); (2) transfers the current Office of Policy Coordination (RM10) function to the newly established Office of Policy and Planning (RMA); and (3) abolishes the Office of Policy and Coordination (RM10).

Chapter RM—Maternal and Child Health Bureau

Section RM—00, Mission

To provide national leadership, in partnership with key stakeholders, to improve the physical and mental health, safety and well-being of the maternal and child health (MCH) population which includes all of the nation's women, infants, children, adolescents, and their families, including fathers and children with special health care needs.

Section RM–10, Organization

Delete the organization for the Maternal and Child Health Bureau (RM) in its entirety and replace with the following:

The Maternal and Child Health Bureau (RM) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Maternal and Child Health Bureau includes the following components:

(1) Office of the Associate Administrator (RM);

(2) Office of Operations and Management (RM1);

(3) Office of Policy and Planning (RMA);

(4) Division of Services for Children with Special Health Needs (RM2);

(5) Division of Child, Adolescent and Family Health (RM3);

(6) Division of MCH Workforce Development (RM4);

(7) Division of Healthy Start and Perinatal Services (RM5);

(8) Division of State and Community Health (RM6);

(9) Division of Home Visiting and Early Childhood Systems (RM8); and

(10) Office of Epidemiology and Research (RM9).

Section RM–20, Functions

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (RM). Specifically, this notice: (1) Establishes the Office of Policy and Planning (RMA); (2) transfers the Office of Policy Coordination (RM10) function to the newly established Office of Policy and Planning (RMA); and (3) abolishes the Office of Policy and Coordination (RM10).

Delete the function for the Office of Policy Coordination (RM10), and replace in its entirety.

Office of Policy and Planning (RMA)

The Office of Policy and Planning (OPP) serves as the Maternal and Child Health Bureau (MCHB) focal point for the development of MCHB policy and program planning. Specifically, the Office: (1) Supports the Office of the Associate Administrator in identifying, planning, and implementing policy and program priorities across MCHB; (2) works closely with the Office of the Associate Administrator to develop strategic plans, facilitate program alignment, and support special initiatives; (3) advises and assists in the development, coordination and management of program and policy documents, and responses to departmental and HRSA initiatives; and (4) coordinates with other components within HRSA and HHS, federal agencies, state and local governments, and other public and private organizations on issues affecting MCHB programs and policies.

Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: July 15, 2015.

James Macrae,

Acting Administrator.

[FR Doc. 2015–18415 Filed 7–24–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel Validation of Pediatric Patient Reported Outcomes in Chronic Diseases.

Date: August 13–14, 2015

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Kan Ma, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 814, Bethesda, MD 20892, 301–451–4838, *mak2@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: July 21, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–18244 Filed 7–24–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel; E01 Parkinson's Disease Biomarker Samples.

Date: July 30, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3205, MSC 9529, Bethesda, MD 20892–9529, 301–435–9223, *joel.saydoff@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; K99/R00 Review.

Date: July 31, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Elizabeth A Webber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–1917, *webbere@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: July 21, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–18245 Filed 7–24–15; 8:45 am]

BILLING CODE 4140–01–P

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: September 1–2, 2015.

Closed: September 1, 2015, 1:00 p.m. to 4:00 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: September 2, 2015, 8:00 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.