agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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 collection of information in this guidance was approved under OMB control no. 0910–0635.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*.

Dated: July 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16702 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0312]

Guidance for Institutional Review Boards, Frequently Asked Questions—Institutional Review Board Registration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Institutional Review Boards (IRBs), Frequently Asked Questions — IRB Registration.'' This guidance is intended to assist IRBs in complying with the new requirement for IRB registration. This new rule requires each IRB in the United States that reviews FDA-regulated research to register using an Internet-based registration system that is maintained by the Department of Health and Human Services (HHS). This registration system is a modification of the one currently used by the Office for Human Research Protections (OHRP) for registration of IRBs that are designated by institutions under Federalwide Assurances (FWAs). OHRP has issued a similar rule requiring IRBs designated by institutions under FWAs to register or update their registration information using this modified system.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written comments on this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jean Toth-Allen, Office of Science and Health Coordination/Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1585.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document for IRBs entitled, ''Guidance for Institutional Review Boards (IRBs), Frequently Asked Questions — IRB Registration.'' This guidance is intended to assist IRBs in complying with the new requirement for IRB registration under amended 21 CFR 56.106, which is effective July 14, 2009. Registration will be accomplished through a modified version of the Internet-based registration system used by OHRP for registration of IRBs that are designated by institutions under FWAs. This guidance document addresses basic information, such as why FDA issued the new rule, which IRBs are subject to the new regulation, the type of information to be provided when registering, and implications of non-compliance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is being issued as a level 1 guidance for immediate implementation in accordance with 21 CFR 10.115(g). Prior public participation is not feasible and FDA believes the guidance is necessary to help IRBs better understand their responsibilities under the new registration rule, which will go into effect on July 14, 2009.

II. The Paperwork Reduction Act of 1995

This guidance refers to a previously approved collection of information required by the FDA new final rule on registration requirements. This collection of information is 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 collection of information in 21 CFR 56.106(b) has been approved under 0990–0279.

III. Comments

Interested persons may submit written or electronic comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/oc/gcp/draft.html* or *http://www.fda.gov/ohrms/dockets/default.htm*

Dated: July 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16703 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–01–S

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 Minority Biomedical Research Support.

Date: July 23, 2009.

Time: 1 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AN18, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Margaret J. Weidman, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18B, Bethesda, MD 20892. 301–594–3663. *weidmanma@nigms.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel ZGM1–BRT–0–CO.

Date: August 3, 2009.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AN18, 45 Center Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Margaret J. Weidman, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18B, Bethesda, MD 20892. 301–594–3663. *weidmanmanigms.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel ARRA Funds—ZGM1–GDB–7–CR.

Date: August 7, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AN12, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lisa A. Dunbar, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892. 301–594–2849. *dunbarl©mail.nih.gov*.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel Trauma/Burn Program Projects.

Date: August 11, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AS13, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Meredith D. Temple-O'Connor, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12C, Bethesda, MD 20892. 301–594–2772. *templeocm@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; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: July 7, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–16569 Filed 7–13–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): RFA–DP09–101SUPP09: Health Promotion and Disease Prevention Research Centers: Special Interest Project Competitive Supplements (SIPS) (U48 Panels A–M)

This meeting is for the initial review of applications.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Dates and Times:

July 29, 2009, 9 a.m.–5 p.m. Closed.
July 30, 2009, 9 a.m.–5 p.m. Closed.
July 31, 2009, 10 a.m.–4 p.m. Closed.
August 3, 2009, 9 a.m.–5 p.m. Closed.
August 4, 2009, 9 a.m.–5 p.m. Closed.

Place: W Hotel, 3377 Peachtree Road, NE., Atlanta, GA 30326, 770–488–3024 and teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of the application received in response to ''RFA–DP09–101SUPP09: Health Promotion ans Disease Prevention ResearchCenters: Special Interest Project Competitive Supplements (SIPS) (U48Panels A–M).''

For More Information Contact: Brenda Colley Gilbert, PhD, Director, Extramural Research Program Office, CCHP, 4770 Buford Highway, M/S K–92, Atlanta, GA 30341; 770–488–6295.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 8, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–16647 Filed 7–13–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Digestive Diseases and Nutrition Mentored Applications Review.

Date: July 31, 2009.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *ls38z@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.