new Information Sheet Guidances as needed.

In the Federal Register of July 29, 2008 (73 FR 43940), FDA announced the availability of a draft version of the guidance entitled, “Draft Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions—Statement of Investigator (Form FDA 1572).” The July 2008 guidance gave interested persons an opportunity to submit comments through September 29, 2008. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated in the guidance. As a result of the public comments and editorial changes, the guidance is clearer than the draft version.

This information sheet guidance is being issued consistent with FDA’s GCP’s regulation (21 CFR 10.115). The information sheet guidance represents the agency’s current thinking on completing the Form FDA 1572. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach 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 found in FDA regulations. These collections of information 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 for Form FDA 1572 have been approved under OMB Control No. 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/Guidance7ComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.
under Section III–A–1 of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: Notice of a discussion of a proposed action under Section III–A–1 published on May 24, 2010 (75 FR 28811) is withdrawn. The discussion that was to be held at the June 16–17, 2010 meeting of the NIH Recombinant DNA Advisory Committee has been deferred at the request of the principal investigator.

FOR FURTHER INFORMATION CONTACT: OBA by e-mail at oba@od.nih.gov, or telephone at 301–496–9838, if you have questions, or require additional information.


Jacqueline Corrigan-Curay,
Acting Director, Office of Biotechnology Activities, National Institutes of Health.

[FR Doc. 2010–13448 Filed 6–3–10; 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 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: Center for Scientific Review Special Emphasis Panel; ARRA: AIDS and Related Research Competitive Revisions.

Date: June 17, 2010.

Time: 4 p.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892
(Telephone Conference Call).

Contact Person: Mark P. Rubert, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892. 301–435–1775, rubertm@csr.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: Center for Scientific Review Special Emphasis Panel; Tooth Development, Mobility and Mineralization.

Date: June 23, 2010.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892
(Telephone Conference Call).

Contact Person: Priscilla B. Chen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892. (301) 435–1787, chenp@csr.nih.gov.


Dated: June 2, 2010.

Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–13453 Filed 6–3–10; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, June 21, 2010, 6:30 p.m. to June 23, 2010, 12 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892 which was published in the Federal Register on May 11, 2010, FR 26267–26268.

This Federal Register Notice is being amended to change the date, times, and location of the meeting of the Ad Hoc Subcommittee on Experimental Therapeutics to June 22, 2010 from 12 p.m. to 1 p.m. at the National Institutes of Health, Building 31, 31 Center Drive, Conference Room 7, Bethesda, MD 20892 and to add the meeting of the Subcommittee on Clinical Investigations to June 21, 2010 from 6 p.m. to 7:30 p.m. at Embassy Suites, Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–13451 Filed 6–3–10; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Coordination Core for Programs to Increase Diversity Among Individuals Engaged in Health-Related Research (PRIDE).

Date: June 16, 2010.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Stephanie J Webb, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–435–0291, stephanie.webb@nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Atherosclerosis Risk in Communities (ARIC) Study—Field Centers.

Date: June 24, 2010.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892
(Telephone Conference Call).

Contact Person: Tony L Creazzo, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, creazzot@mail.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Atherosclerosis Risk in Communities (ARIC) Study—Central Laboratory Center.

Date: June 24, 2010.

Time: 3:30 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892
(Telephone Conference Call).

Contact Person: Tony L Creazzo, PhD, Scientific Review Officer, Review Branch/