and telephone number. Those without Internet access should contact Nilsa Loyo-Berrios to register (see *Contact Persons*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on August 28, 2012. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Web cast participants will be sent technical system requirements after registration and will be sent connection access information after August 23, 2012. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to provide an update and obtain stakeholders input on post-approval studies ordered at the time of device approval. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is September 30, 2012.

Regardless of attendance at the public workshop, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 or electronic comments to *http://www.regulations.gov.* 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. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Post-approval studies (PAS) are imposed as conditions of approval for some class III devices regulated under premarket approval (PMA) regulations and are an important public health tool for developing additional evidence on device performance in the postmarket setting. In order for PAS to be most effective, studies must be well-designed, scientifically sound, meaningful and feasible, and must provide complete and timely information. PMA conditions of approval studies are constructed to ask for specific, detailed data in a subsequent PAS relating to unanswered questions in premarket data. However, there are often opportunities for leveraging the design and conduct of PAS, enhancing its utility to other important stakeholders. In addition to the direct role of PMA holders, the role of other public health partners is expanding, as evidenced by a number of efforts external to CDRH that are directly or indirectly involved in collecting and analyzing data relevant to estimating medical device use and risk and in communicating risk to target populations. To ensure a successful PAS program, CDRH, regulated industry, clinical researchers, and other stakeholders must remain well-informed and engaged in continuous dialogue regarding the design, implementation, reporting, and use of PAS and the resultant data. Further, it is the Center's desire to ensure this dialogue results in studies that maximize the public health impact by producing data that is informative to a range of stakeholders.

II. Topics for Discussion at the Public Workshop

We intend to discuss a large number of issues at the workshop, including, but not limited to the following: (1) PAS within the Total Product Life Cycle, (2) best practices and improvement of PAS implementation strategies, (3) PAS impact on public health and medical device innovation, and (4) opportunities for innovative uses of PAS data.

Dated: August 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20469 Filed 8–20–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Translational Research.

Date: September 19, 2012.

Time: 11:00 a.m. to 5:00 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: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Diabetes Ancillary Studies.

Date: October 10, 2012.

Time: 2:00 p.m. to 4:00 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: D.G. Patel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard,

Bethesda, MD 20892–5452, (301) 594–7682, *pateldg@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 15, 2012.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–20560 Filed 8–20–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; MSM Program Review.

Date: September 21, 2012.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Suite 951, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Manana Sukhareva, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging, And Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301–451–3397, *sukharem@mail.nih.gov.*

Dated: August 15, 2012.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–20557 Filed 8–20–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

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.

Name of Committee: Recombinant DNA Advisory Committee.

Date: September 12, 2012.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: The NIH Recombinant DNA Advisory Committee (RAC) will discuss selected human gene transfer protocols. Please view the meeting agenda at *http://oba.od.nih.gov/rdna_rac/rac_meetings.html* for more information.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Chezelle George, Office of Biotechnology Activities, Office of Science Policy/OD, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892, 301–496–9838, *georgec@od.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.

OBA will again offer those members of the public viewing the meeting via webcast (see OBA Meetings Page available at the following URL: *http://oba.od.nih.gov/rdna_rac/rac_meetings.html*) to submit comments during the public comment periods. Individuals wishing to submit comments should use the comment form, which will accommodate comments up to 1500 characters, and will be available on the OBA web site during the meeting (see OBA Meetings Page). Please limit your comment to a statement that can be read in one to two minutes. Please include your name and affiliation with your comment. Only comments submitted through the OBA Web site will be read.

OBA will read comments into the record during the public comment periods as stated on the agenda. It is not unusual for the meeting to run ahead or behind schedule due to changes in the time needed to review a protocol. It is advisable to monitor the webcast to determine when public comments will be read. Each public comment period follows a specific discussion item. OBA will read comments that are related to the protocol or presentation under discussion at that time. General comments unrelated to a specific agenda item will be read at the end of the meeting, time permitting. Comments submitted by email through the OBA Web site will follow any comments by individuals attending the meeting. Comments will be read in the order received and your name and affiliation will be read with the comments. Please note OBA may not be able to read every comment received in the time allotted for public comment. Comments not read will become part of the public record.

Information is also available on the Institute's/Center's home page: *http://oba.od.nih.gov/rdna/rdna.html,* where an agenda and any additional information for the meeting will be posted when available. OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 14, 2012.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–20556 Filed 8–20–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as