participation in the MDDT Pilot Program by submitting a proposal to *MDDT@fda.hhs.gov.* FDA intends to acknowledge receipt of nominations via email.

A submitter's proposal for the MDDT Pilot Program should include the following information to assist FDA in processing and responding to nominations:

- A cover letter and a brief statement explaining why the tool is an appropriate candidate for the MDDT Pilot Program as described under section II., B. Appropriate Candidates; and
- A description of the tool, the proposed context of use, a synopsis of the available evidence and plans for additional evidence gathering, and an assessment of the advantages or disadvantages related to the capabilities and limitations of the tool for the proposed context of use.

2. *Submitter Notification.* FDA intends to notify the submitter via email whether or not the tool is an appropriate candidate for the MDDT Pilot Program within approximately 30 days of receipt of the complete information.

3. *Pre-qualification Plan.* If the nominee is deemed an appropriate candidate, the submitter will be notified by FDA and invited to submit a pre-qualification plan within approximately 30 days of being notified by the FDA that its nominee was accepted. One way to present the pre-qualification plan is included in Appendix 1 of the MDDT draft guidance. FDA recommends the pre-qualification and qualification plans be submitted in accordance with FDA guidance entitled ''Medical Devices: Pre-Submission Program and Meetings with FDA Staff'' (*www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf*) as the process for the MDDT pilot program is expected to be modeled after the Pre-Submission Program.

4. *Pre-qualification Meeting.* FDA intends to meet with the submitter, either in person or by phone, in accordance with the process outlined in the FDA guidance on ''Medical Devices: Pre-Submission Programs and Meetings With FDA Staff.'' The qualification review team (which may include FDA as well as external expertise, where appropriate) will interact with the submitter to identify the amount and type of data or information needed for qualification of the tool for the proposed context of use.

5. *FDA Review.* Under the MDDT Pilot Program, the Agency intends to work interactively with submitters as follows:

- Where appropriate, FDA may seek input from external individuals or groups for specific expertise, consistent with all applicable statutory and regulatory requirements, including those respecting confidentiality.
- During the process for MDDT qualification, FDA intends to interact with submitters to efficiently determine the amount and type of information needed to support qualification for a specific tool and context of use, and as needed for clarification or to request additional information.
- When the submitter has the data and information necessary for a complete qualification package, they may submit it to justify qualification of the tool for the proposed context of use. FDA intends to hold a qualification meeting or teleconference to facilitate discussion once the package has been reviewed.

D. Duration of the MDDT Pilot Program

FDA intends to accept requests for participation in the MDDT Pilot Program until such time that the MDDT draft guidance is finalized. FDA may decide to terminate the MDDT Pilot Program at any time or extend the MDDT Pilot Program. The decision to terminate or extend the MDDT Pilot Program will be announced in the **Federal Register**. FDA may also decide to modify the MDDT Pilot Program while it is in effect. Any significant modifications will also be announced in the **Federal Register**.

E. Evaluation

FDA intends to use the experience gained from the MDDT Pilot Program to inform the final version of the MDDT guidance and processes.

III. Paperwork Reduction Act of 1995

This notice contains information collection that 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 collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078 (Investigative Device Exemption); the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231 (Premarket Approval); the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120 (Premarket Notification); and the collections of information in 21 CFR part 809 have been approved under OMB control number 0910–0485.

Dated: August 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19360 Filed 8–14–14; 8:45 am]

BILLING CODE 4164–01–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; Small Grants to Promote Diversity.

Date: September 16, 2014.

Time: 9 a.m. to 2 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: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 750, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–8886, *sanoviche@mail.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–13–266–NIDDK Program Project (P01)–ANCA Glomerulonephritis.

Date: October 1, 2014.

Time: 11 a.m. to 4 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: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases

Special Emphasis Panel; Ancillary Study to the Intestinal Stem Cell Consortium.

Date: October 2, 2014.

Time: 10 a.m. to 11:30 a.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: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.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 11, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–19319 Filed 8–14–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34).

Date: September 8, 2014.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3124, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Uday K. Shankar, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 3246, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–594–3193, *uday.shankar@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Clinical Trial Planning Grant (R34).

Date: September 10, 2014.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3124, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Uday K. Shankar, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 3246, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–594–3193, *uday.shankar@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 11, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–19321 Filed 8–14–14; 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; P41 MRI-Optical Review (2015/01).

Date: November 11–13, 2014.

Time: 6 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton University City, 3549 Chestnut Street, Philadelphia, PA 19104.

Contact Person: Ruth Grossman, DDS, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 960, Bethesda, MD 20892, 301–496–8775, *grossmanrs@mail.nih.gov.*

Dated: August 11, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–19320 Filed 8–14–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Primary and Behavioral Health Care Integration Program (OMB No. 0930–0340)—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services, (CMHS) is requesting a revision from the Office of Management and Budget (OMB) for data collection activities associated with their Primary and Behavioral Health Care Integration (PBHCI) Program. Specifically, SAMHSA is requesting approval to only collect information on physical health indicators through a supplemental module to the TRansforming ACcountability (TRAC) System and grantee quarterly reports. The current data collection (OMB No. 09300340) expires on September 30, 2014.

The purpose of the PBHCI grant program is to improve the overall wellness and physical health status of people with serious mental illnesses (SMI), including individuals with co-occurring substance use disorders, by supporting communities to coordinate and integrate primary care services into publicly-funded community mental health and other community-based behavioral health settings. The program's goal is to improve the physical health status of adults with serious mental illnesses (and those with co-occurring substance use disorders) who have or are at risk for co-occurring primary care conditions and chronic diseases. The program's objective is to