II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). This guidance represents the current thinking of FDA on two-phased CMC technical sections. 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.

III. 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 in 21 CFR part 514 and section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control numbers 0910–0032 and 0910–0669, respectively.

IV. 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.*

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: August 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21583 Filed 8–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before October 1, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title: State and Territorial Health Disparities Survey Abstract: The Office of Minority Health (OMH), Office of the Secretary (OS) is requesting approval from the Office of Management and Budget (OMB) for a new data collection activity for the State and Territorial Health Disparities Survey (STHD Survey).

OMH has a long history of collaborating with states to improve minority health outcomes and reduce health and health care disparities. A strong partnership with state and territorial offices is a key to continue progress toward eliminating health disparities. To best facilitate continued partnerships, OMH needs information about the current activities, challenges, and resources within state and territorial offices of minority health. The State and Territorial Health Disparities Survey is intended to support OMH informational needs by collecting, organizing, and presenting a variety of information about states and U.S. territories, including the current status of minority health and health disparities, the organization and operation of state and territorial offices of minority health, and state/territorial implementation of federal standards and evidence-based practices designed to address disparities and improve minority health. The STHD Survey, which will focus on the activities, staffing, and funding of State Minority Health Entities, is part of a larger project to catalog the extent of health disparities and the activities underway to reduce them in each state and U.S. territory. The STHD Survey supports OMH's goals of working with states and territories to improve the health of racial and ethnic minority populations and eliminate health disparities. While existing, state/territorial-specific information sources (*e.g.,* quantitative data points available from the Agency for Healthcare Research and Quality's *National Healthcare Disparities Report State Snapshots*) offer important facts about the status of health disparities, they do not provide context around the efforts underway to reduce them.

Likely Respondents- Data will be collected using semi-structured telephone interviews with state/territorial minority health entity directors (or their designees) in approximately 54 states and territories (50 states plus the District of Columbia and the U.S. territories of Guam, Puerto Rico, and the U.S. Virgin Islands). The purpose of this interview is to collect qualitative information about state/territory program goals and activities, partnerships, and organizational structure, as well as quantitative data elements on staffing and funding.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondents	Average hours per response	Total burden hours
State and Territorial Survey	54	1	1.5	81
Total				81

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015–21576 Filed 8–31–15; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 Nursing Research Special Emphasis Panel—Training and Career Development.

Date: September 29, 2015.

Time: 2:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Division of Extramural Activities, National Institute of Nursing Research, National Institutes of Health, One Democracy Plaza, Room 703, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Yujing Liu, Ph.D., MD, Chief, Office of Review, Division of Extramural Activities, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 710, Bethesda, MD 20892, (301) 451–5152, *yujing_liu@nih.gov*.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel—Biobehavioral and Technological Interventions to Attenuate Cognitive Decline in Individuals with Cognitive Impairment or Dementia.

Date: October 1, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications

Place: Division of Extramural Activities, National Institute of Nursing Research, National Institutes of Health, One Democracy Plaza, Room 703, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Tamizchelvi Thyagarajan, Ph.D., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, Suite 710, Bethesda, MD 20892, (301) 594–0343, *tamizchelvi.thyagarajan@nih.gov*.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel—Training and Career Development.

Date: October 7, 2015.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Division of Extramural Activities, National Institute of Nursing Research, National Institutes of Health, One Democracy Plaza, Room 703, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Yujing Liu, Ph.D., MD, Chief, Office of Review, National Institute of Nursing Research, National Institutes of Health, Suite 710, Bethesda, MD 20892, (301) 451–5152, *yujing_liu@nih.gov*.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel—Self-Management for Health in Chronic Conditions.

Date: October 8, 2015.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, Room 703, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Tamizchelvi Thyagarajan, Ph.D., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, Suite 710, Bethesda, MD 20892, (301) 594–0343, *tamizchelvi.thyagarajan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: August 26, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–21530 Filed 8–31–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Fogarty International Center Advisory Board, September 14, 2015, 01:00 p.m. to September 15, 2015, 03:00 p.m., National Institutes of Health, 16 Center Drive, Lawton L. Chiles International House, Bethesda, MD, 20892 which was published in the **Federal Register** on August 11, 2015, 80 FR 48115.

The meeting is being amended to change the time of the meeting. The closed session will be Sept. 14 from 1:00 p.m.–2:15 p.m., then the open session @ 2:30 p.m. and adjourn @ 5:15 p.m. Open session Sept.15 from 9 a.m. and adjourn @ 12:00 noon. The meeting is partially closed to the public.

Dated: August 26, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–21529 Filed 8–31–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Mental Health, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Mental Health.

Date: September 29–30, 2015.

Time: September 29, 2015, 9:00 a.m. to 5:25 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Rooms GE610/GE640, Building 35A Convent Drive Bethesda, MD 20892.

Time: September 30, 2015, 9:00 a.m. to 4:05 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Rooms GE620/GE630 and GE640, Building 35A Convent Drive, Bethesda, MD 20892.

Contact Person: Jennifer E Mehren, Ph.D., Scientific Advisor, Division of Intramural Research Programs, National Institute of Mental Health, NIH, 35A Convent Drive, Room GE 412, Bethesda, MD 20892–3747, 301–496–3501, *mehrenj@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)