

Because listing outside of the annual requirement is voluntary, FDA estimates that annually 78 percent of 510(k)s will continue to be listed outside of the annual requirement. FDA estimates that 4,080 510(k)s may be listed outside of the annual registration cycle. FDA estimates that it will take approximately 15 minutes for each listing, for a total reporting burden of 1,020 hours.

FDA estimates it will have 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. FDA reached this estimate by identifying the number of unique 510(k) device listings entered in FURLS between fiscal years 2009 and 2014 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (6), and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3). The draft guidance identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance. FDA estimates it will take a party approximately 4 hours to locate and submit information to establish the transfer of the 510(k) clearance, resulting in 8,132 burden hours for those 2,033 parties claiming to be 510(k) holders. FDA reached this estimate based on its expectation of the amount of time it will take a party to locate the information, copy it, and submit a copy to FDA.

The burden estimate does not include the maintenance of records used to document transferring a premarket notification (510(k)) clearance. Based on available information, FDA believes that the maintenance of these records is a usual and customary part of normal business activities. For example, in the ordinary course of business, supporting documents should be kept to verify asset information for calculating the annual depreciation or calculating gain or loss on sale of an asset on a businesses' tax return. Therefore, this recordkeeping requirement creates no additional paperwork burden.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807 (registration and listing) are approved under OMB control number 0910-0625; the collections of information in 21 CFR part 807 subpart E (premarket notification submission) have been approved under OMB control number 0910-0120, and collections of information in 42 CFR 493.17 have been approved under OMB control number 0910-0607.

Dated: March 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-04995 Filed 3-12-18; 8:45 am]

BILLING CODE 4164-01-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(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee on Research on Women's Health.

The meeting will be open to the public as indicated below, 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.

A portion of 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: Advisory Committee on Research on Women's Health.

Closed: April 17, 2018, 2:30 p.m. to 4:45 p.m.

Agenda: To evaluate the Sex/Gender Administrative Supplements program proposed for ORWH's Strategic Plan.

Open: April 18, 2018, 9:00 a.m. to 1:30 p.m.

Agenda: Opening Remarks, Director's Report, NIH Legislative Update, Strategic Plan Update, and Scientific Presentations.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Elizabeth Spencer, R.N., Deputy Director, Office of Research on Women's Health, Executive Secretary, ACRWH, National Institutes of Health, 6707 Democracy Blvd., Room 7W444, Bethesda, MD 20817, 301-402-1770 elizabeth.spencer@nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short

description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: www4.od.nih.gov/orwh/, where an agenda and any additional information for the meeting will be posted when available.

(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: March 6, 2018.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-04954 Filed 3-12-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Child Health and Human Development Special Emphasis Panel—R41 applications.

Date: April 4, 2018.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892, (301) 435-6680, skandasa@mail.nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: April 9, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda Downtown, 7335 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Kimberly Lynette Houston, MD, Scientific Review Officer, Division of Scientific Review, OD, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892, 301.827.4902, kimberly.houston@nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: April 10, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda Downtown, 7335 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Kimberly Lynette Houston, MD, Scientific Review Officer, Division of Scientific Review, OD, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892, 301.827.4902, kimberly.houston@nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: April 10, 2018.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20892, (301) 435-6680, skandasa@mail.nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: April 13, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Peter Zelazowski, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Bethesda, MD 20892-7510, 301-435-6902, peter.zelazowski@nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: April 16-17, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Dennis E. Leszczynski, Ph.D., Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Bethesda, MD 20892, (301) 435-6884, leszczyd@mail.nih.gov.

(Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 7, 2018.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-04961 Filed 3-12-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Center for Substance Abuse Treatment (CSAT) National Advisory Council will meet on March 26, 2018, 2:00 p.m.-3:00 p.m. (EDT) in a closed teleconference meeting.

The meeting will include discussions and evaluations of grant applications reviewed by SAMHSA's Initial Review Groups, and involve an examination of confidential financial and business information as well as personal information concerning the applicants. Therefore, the meeting will be closed to the public as determined by the SAMHSA Assistant Secretary for Mental Health and Substance Use in accordance

with Title 5 U.S.C § 552b(c)(4) and (6) and Title 5 U.S.C. App. 2, 10(d).

Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at <http://www.samhsa.gov/about-us/advisory-councils/csat-national-advisory-council> or by contacting the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below).

Council Name: SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

Date/Time/Type: March 26, 2018, 2:00 p.m.-3:00 p.m. EDT, Closed.

Place: SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857.

Contact: Tracy Goss, Designated Federal Officer, CSAT National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276-0759, Fax: (240) 276-2252, Email: tracy.goss@samhsa.hhs.gov.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2018-04975 Filed 3-12-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2018-0018; OMB No. 1660-0131]

Agency Information Collection Activities: Proposed Collection; Comment Request; Threat and Hazard Identification and Risk Assessment (THIRA)—Stakeholder Preparedness Review (SPR) Reporting Tool

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning this annual requirement for the U.S. Department of Homeland Security (DHS), FEMA to identify current capability levels for all States, Territories, urban areas, and Tribes receiving non-disaster preparedness grant funds administered by DHS.