

emergency, FDA intends to revise and replace this guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency." 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.

II. 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. 3501-3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information relating to the protection of human subjects and IRBs have been approved under OMB control number 0910-0130; and the collections of information in FDA's guidance for industry on "Individual Patient Expanded Access Applications: Form FDA 3926" have been approved under OMB control number 0910-0814.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>, <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, or <https://www.regulations.gov>.

Dated: June 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-12429 Filed 6-8-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a virtual meeting. The meeting will be open to the public. For this meeting, the TBDWG will review the draft 2020 report to the HHS Secretary and Congress and review and approve graphics and images for the report. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursuant to such research; federal activities related to tick-borne diseases; and gaps in tick-borne disease research.

DATES: The meeting will be held online via webcast on July 8, 2020, from 9:00 a.m. to 5:30 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG webpage at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-7-8/index.html> when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC 20024. Email: tickbornedisease@hhs.gov; Phone: 202-795-7608.

SUPPLEMENTARY INFORMATION: Please register for the virtual meeting at https://kauffmaninc.adobeconnect.com/tbdwg_july2020/event/event_info.html. After registering, you will receive an email confirmation with a personalized link to access the webcast on July 8.

The public will have an opportunity to present their views to the TBDWG orally during the meeting's public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public

comment should review instructions at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-7-8/index.html> and respond by midnight June 24, 2020, ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30 minute session. Written public comments will be accessible to the public on the TBDWG web page prior to the meeting.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with Section 2062 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review federal efforts related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease every two years.

Dated: May 20, 2020.

James J. Berger,

Designated Federal Officer, Tick-Borne Disease Working Group, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020-12432 Filed 6-8-20; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS-4040-0018]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 9, 2020.

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

FOR FURTHER INFORMATION CONTACT: Ed Calimag, ed.calimag@hhs.gov or (202) 690-7569. When submitting comments or requesting information, please include the document identifier 4040-0018-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collections: SF-428 Tangible Personal Property Report.

Type of Collection: Extension.

OMB No. 4040-0018.

Abstract: Reporting on the status of Federally owned property, including disposition, is necessitated in 2 CFR part 215, the “Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations”, and the “Uniform Administrative Requirements for Grants and Agreements with State and Local Governments”, Additionally, Public Law 106-107, the Federal Financial Assistance Management Improvement Act requires that agencies “simplify Federal financial assistance application and reporting requirements.” 31 U.S.C. 6101, Section 3.

Agencies are currently using a variety of forms to account for both federally owned and grantee owned equipment and property. During the public

consultation process mandated by Public Law 106-107, grant recipients requested a standard form to help them submit appropriate property information when required. The Public Law 106-107 Post Awards Subgroup developed a new standard form, the Tangible Personal Property Report, for submission of the required data. The form consists of the cover sheet (SF-428), three attachments to be used as required: Annual Report, SF-428-A; Final Report, SF-428-B; Disposition Request/Report, SF-428-C and a Supplemental Sheet, SF-428S to provide detailed individual item information when required. The IC expires on 6/30/2020. We are seeking an extension of this information collection and a three-year clearance.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SF-428 Tangible Personal Property Report	2000	1	1	2000
Total	2000	2000

Sherrette A. Funn,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2020-12401 Filed 6-8-20; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Eye Institute Special Emphasis Panel; NEI Translational Research Program (TRP) to Develop Novel Therapies and Devices for the Treatment of

Visual System Disorders and R13 Conference Grant Applications.

Date: July 30, 2020.

Time: 10:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ashley Fortress, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20817, (301) 451-2020, *ashley.fortress@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: June 4, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-12458 Filed 6-8-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 on Drug Abuse Special Emphasis Panel; Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trials Optional).

Date: July 9, 2020.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neurosciences Center Building, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ivan K. Navarro, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 6001 Executive Boulevard, Room 4242, MSC 9550, Bethesda, MD 20892 (301) 827-5833, *ivan.navarro@nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; R13 Conference Grant Review.