

the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by email by emailing ORA at [orapolicystaffs@fda.hhs.gov](mailto:orapolicystaffs@fda.hhs.gov). See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Christopher Henderson, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857, [Christopher.Henderson@fda.hhs.gov](mailto:Christopher.Henderson@fda.hhs.gov), 240-402-8186; or Ben Firschein, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993-0002, [Ben.Firschein@fda.hhs.gov](mailto:Ben.Firschein@fda.hhs.gov), 240-402-8186.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Conducting Remote Regulatory Assessments—Questions and Answers." FDA is issuing the draft guidance to describe the Agency's current thinking regarding its use of RRAs in order to help increase industry's understanding of RRAs, thereby facilitating FDA's process for conducting remote assessments. RRAs include requests for records and other information for FDA review and interactive evaluations of an FDA-regulated establishment or product with the use of, for example, livestreaming video. RRAs can be either voluntary or mandated. FDA has used RRAs to conduct oversight, mitigate risk, meet critical public health needs, and help maximize compliance with

applicable FDA requirements, for all types of FDA-regulated products.

For example, during the Coronavirus Disease 2019 (COVID-19) pandemic, FDA has used RRAs to inform approval and licensing decisions, verify corrective actions for establishments with an acceptable compliance status, and gain compliance insight into establishments that FDA has been unable to inspect. This experience has identified significant benefits of using RRAs to FDA, regulated industry, and the public. For these and other reasons, FDA is issuing this draft guidance to describe its intention to, when appropriate, continue to use RRAs outside of the COVID-19 public health emergency and for all FDA-regulated product types.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Conducting Remote Regulatory Assessments." 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

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

##### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>.

Dated: July 19, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-new]

#### Agency Information Collection Request: 60-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 September 23, 2022.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 264-0041.

#### FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov), or call (202) 264-0041 the Reports Clearance Officer.

**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 Collection:** Teen Pregnancy Prevention Fiscal Year 2020/2021 Tier 1 and Tier 2 Implementation Study.

**Type of Collection:** New collection.

**OMB No.** 0990-NEW-Office of Population Affairs.

**Abstract:** The Office of Population Affairs (OPA), U.S. Department of Health and Human Services (HHS) is requesting 2 years of approval by OMB on a new collection. The Teen Pregnancy Prevention (TPP) Tier 1 and Tier 2 Implementation Study will document how 75 grantees funded in 2020 and 2021 are implementing their grant strategies to reduce rates of teen pregnancy and sexually transmitted infections in their selected communities or priority areas. OPA anticipates that grantees will employ diverse strategies working with partner organizations within communities to implement their teen pregnancy prevention projects. To document approaches and experiences of each grantee, a lead staff member in each grantee organization and up to one other staff member will be interviewed during an in-person or virtual site visit. Up to two staff members from key grantee partner organizations will be interviewed for 31 of the 62 Tier 1 grantees and all 13 Tier 2 grantees.

*Type of Respondent:* Interview participants will include up to 124 Tier 1 grantee staff members, 62 Tier 1 grantee partner organization staff

members, 26 Tier 2 grantee staff members and 26 Tier 2 grantee partner organization staff members.  
*Frequency:* One time.

*Affected Parties:* Public and private businesses.

#### ANNUALIZED BURDEN HOUR TABLE

| Forms<br>(if necessary)              | Respondents<br>(if necessary)            | Number of<br>respondents | Number of<br>responses per<br>respondents | Average<br>burden per<br>response | Total burden<br>hours |
|--------------------------------------|--|--------------------------|---|-----------------------------------|-----------------------|
| Tier 1 Grantee Interview Guide ..... | Tier 1 grantee director and other staff. | 124                      | 1   | 2                                 | 248                   |
| Tier 1 Partner Interview Guide ..... | Tier 1 grantee partner staff .....       | 62                       | 1   | 1                                 | 62                    |
| Tier 2 Grantee Interview Guide ..... | Tier 2 grantee director and other staff. | 26                       | 1   | 2                                 | 52                    |
| Tier 2 Partner Interview Guide ..... | Tier 2 grantee partner staff .....       | 26                       | 1   | 1                                 | 26                    |
| Total .....                          | .....                                    | .....                    | 1   | .....                             | 388                   |

**Sherrette A. Funn,**

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

[FR Doc. 2022-15792 Filed 7-22-22; 8:45 am]

**BILLING CODE 4150-34-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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 Cancer Institute Special Emphasis Panel NCI Informatics Technologies for Cancer Research.

*Date:* September 8–9, 2022.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850 (Telephone Conference Call).

*Contact Person:* Shuli Xia, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20852, 240-276-5460, [shuli.xia@nih.gov](mailto:shuli.xia@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel IMAT Biospecimen Research.

*Date:* September 16, 2022.

*Time:* 10 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850 (Telephone Conference Call).

*Contact Person:* Shuli Xia, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20852, 240-276-5256, [shuli.xia@nih.gov](mailto:shuli.xia@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel Transition Career Development Award (K22) and Institutional Training and Education (T32, R25).

*Date:* September 22, 2022.

*Time:* 10 a.m. to 7 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850 (Telephone Conference Call).

*Contact Person:* Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, 240-276-6368, [Stoicaa2@mail.nih.gov](mailto:Stoicaa2@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel Innovative Molecular and Cellular Analysis Technologies.

*Date:* October 5, 2022.

*Time:* 10 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W246, Rockville, Maryland 20850 (Telephone Conference Call).

*Contact Person:* Jun Fang, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer

Institute, NIH, 9609 Medical Center Drive, Room 7W246, Rockville, Maryland 20850, 240-276-5460, [jfang@mail.nih.gov](mailto:jfang@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel NCI Program Project (P01) SEP-D.

*Date:* October 6–7, 2022.

*Time:* 9:30 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850 (Telephone Conference Call).

*Contact Person:* Anita T. Tandle, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850, 240-276-5007, [tandlea@mail.nih.gov](mailto:tandlea@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel NCI SPORE (P50) Review I.

*Date:* October 18–19, 2022.

*Time:* 9 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850 (Telephone Conference Call).

*Contact Person:* Michael E. Lindquist, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850, 240-276-5735, [mike.lindquist@nih.gov](mailto:mike.lindquist@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel NCI SPORE (P50) Review II.

*Date:* October 19–20, 2022.

*Time:* 9 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W618, Rockville, Maryland 20850 (Telephone Conference Call).

*Contact Person:* Mukesh Kumar, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH,