| 21 CFR part or guidance | Topic | OMB control No. |
|---|---|---|
| 814, subparts A through E | Premarket approval | 0910–0231 |
| 814, subpart H | Humanitarian Device Exemption | 0910–0332 |
| 812 | Investigational Device Exemption | 0910–0078 |
| ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' | De Novo classification process | 0910–0844 |
| ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff''. | Q-submissions; pre-submissions | 0910–0756 |
| 800, 801, and 809 | Medical Device Labeling Regulations | 0910–0485 |

Dated: June 9, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–12930 Filed 6–15–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0955–0020]**

## 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 August 15, 2022.

**ADDRESSES:** Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0955–0020–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 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:* United States Core Data for Interoperability New Data Element.

*Type of Collection:* Revision.

*OMB No.:* 0955–0020—Office of the National Coordinator for Health Information Technology—Specific program collecting the data (is applicable).

*Abstract:* The Office of the National Coordinator for Health Information Technology is seeking the revision on a previously approved by OMB #0955–0020 information collection request item ''United States Core Data for Interoperability (USCDI) New Data Element Submission Form.'' The USCDI is a standardized set of health data classes and constituent data elements used to support nationwide, interoperable health information exchange. The USCDI Version 1 is the required standard data elements set to which all health IT developers must conform to obtain ONC certification. This certification is required for participation in some federal healthcare payment plans. In order to ensure the USCDI remains current and reflects the needs of the health IT community, ONC has established a predictable, transparent, and collaborative process to solicit broad stakeholder input to expand the USCDI. Anyone, including ONC staff, staff from other federal agencies, and other stakeholders may submit proposals for new data elements and classes. ONC will evaluate each submission and provide feedback to the submitter. ONC will draft a new version of the USCDI based on these submissions and this draft will undergo review by ONC's federal advisory committee, the Health Information Technology Advisory Committee (HITAC), as well as by the general public. Upon approval by the National Coordinator for Health Information Technology, new data classes and data elements from these submissions will be added to the newest version of the USCDI standard for integration into health information technology products such as electronic health records. ONC is seeking approval to continue to collect this information from health IT stakeholders.

*Need and Proposed Use of the Information:* The information collected from this submission system is needed as it will comprise the sum total of the items ONC will evaluate for addition to the next version of the USCDI. The requested data will provide supporting documentation to justify addition of the data elements to the USCDI, and, if the documentation does justify addition to the USCDI, to one of several levels of candidate data elements for future development and consideration. The requested data and ONC's evaluation of the data will be publicly available for review at any time to provide transparency and predictability in the USCDI expansion process. It will contain information about the submitter to allow ONC to provide direct feedback to submitters on ONC's evaluation of such submission.

*Likely Respondents:* Likely respondents to this new submission system will be various health IT stakeholders including health care providers, standards development organizations, health IT developers and vendors as well as members of the HITAC.

The total annual burden hours estimated for this ICR are summarized in the table below.

ANNUALIZED BURDEN HOUR TABLE

| Forms (if necessary) | Respondents (if necessary) | Number of respondents | Number of responses per respondents | Average burden per response | Total burden hours |
|---|---|---|---|---|---|
| USCDI Submission | ..... | 200 | 1 | 20/60 | 67 |

ANNUALIZED BURDEN HOUR TABLE—Continued

| Forms (if necessary) | Respondents (if necessary) | Number of respondents | Number of responses per respondents | Average burden per response | Total burden hours |
|---|---|---|---|---|---|
| Total | | 200 | | | 67 |

**Sherrette A. Funn,**

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

[FR Doc. 2022–12958 Filed 6–15–22; 8:45 am]

**BILLING CODE 4150–45–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Drug Abuse; 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 Institute on Drug Abuse Special Emphasis Panel; Mechanism for Time-Sensitive Drug Abuse Research (R21 Clinical Trial Optional).

*Date:* July 25, 2022.

*Time:* 2:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Soyoun Cho, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC, 6021, Bethesda, MD 20892, (301) 594–9460, *Soyoun.cho@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: June 10, 2022.

**Tyeshia M. Roberson-Curtis,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–12950 Filed 6–15–22; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special Emphasis Panel: Review of the NIH Pathway to Independence Award (K99/R00) Applications.

*Date:* July 7, 2022.

*Time:* 10:30 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

*Contact Person:* Qingdi Quentin Li, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute Environmental Health Sciences, Research Triangle Park, NC 27709, (240) 858–3914, *liquenti@nih.gov.*

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel: Review of the Transition to Independent Environmental Health Research Career Award (K01/K08) Applications.

*Date:* July 8, 2022.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

*Contact Person:* Qingdi Quentin Li, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute Environmental Health Sciences, Research Triangle Park, NC 27709, (240) 858–3914, *liquenti@nih.gov.*

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel: Review of the Outstanding New Environmental Scientist Program.

*Date:* July 26, 2022.

*Time:* 10:30 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

*Contact Person:* Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 984–287–3340, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: June 10, 2022.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–12925 Filed 6–15–22; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S.