ANNUALIZED BURDEN HOUR TABLE

Form name	Number of respondents	Number of responses per respondent	Hours per response	Response burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption	14,000	2	0.5	14,000

Sherrette A. Funn,

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

[FR Doc. 2021–07620 Filed 4–13–21; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0260]

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 June 14, 2021.

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 0990–0260–60D, and project title for reference, to Sherrette 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: Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation.

Type of Collection: Extension.

OMB No. 0990–0260 Office of the Assistant Secretary for Health, Office for Human Research Protections

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation, OMB No. 0990–0260.

Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a Common Rule department or agency has (1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: Assess whether the institution is following the established procedures; ensure that Federal funds are not expended for unapproved human subjects research; and, determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

Likely Respondents: Institutions, institutional review boards and investigators.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Common rule provision	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
.103(b)(5), .113 [Pre-2018 Requirements]/.108(a)(4), .113 [2018 Requirements]—Incident Reporting, Suspension or Termination of IRB approval Reporting	5,200	1	5,200	1	5,200
Total			5,200		5,200

TABLE 2—ESTIMATED ANNUAL IRB RECORDKEEPING BURDEN

Common rule provision	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
.115 [Pre-2018 and 2018 Requirement]—Preparation and documentation of IRB activities	6,000	16	96,000	12	1,152,000
Total			96,000		1,152,000

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
.109(d) [Pre-2018 and 2018 Requirements]—Written notification of IRB approval or disapproval of research	6,000	25	150,000	0.5	75,000
.46.116(a) and (b) (Pre-2018 Requirements)/.46.116 (b), (c) and (d) [2018 Requirements]—Elements of informed consent and broad consent	6,000	25	150,000	0.5	75,000
.46.116(h)—[2018 Requirements]—Posting clinical trial consent form	100	3	300	0.5	150
.117(a) [Pre-2018 and 2018 Requirements]—Documentation of informed consent	6,000	25	150,000	0.5	75,000
.117(c)(2) [Pre-2018 and 2018 Requirements]—Written statement about the research when informed consent documentation is waived	6,000	10	60,000	1	60,000
Total	.....	.....	510,300	.....	285,150

Sherrrette A. Funn,

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

[FR Doc. 2021–07622 Filed 4–13–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Risk, Prevention and Health Behavior Integrated Review Group Addiction Risks and Mechanisms Study Section.

Date: June 14–15, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, *prenticekj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 8, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07610 Filed 4–13–21; 8:45 am]

BILLING CODE 4140–01–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 Council of Councils.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

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: Council of Councils.

Open: May 20, 2021.

Time: 11:00 a.m. to 4:15 p.m.

Agenda: Call to Order and Introductions; Announcements and Updates; Scientific Talks and Other Business of the Committee.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Name of Committee: Council of Councils.

Closed: May 21, 2021.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: Review of Grant Applications.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Open: May 21, 2021.

Time: 11:00 a.m. to 4:05 p.m.

Agenda: NIH Program Updates; Scientific Talks and Other Business of the Committee.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Franziska Grieder, D.V.M., Ph.D., Executive Secretary, Council of Councils, Director, Office of Research Infrastructure Programs, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, 6701 Democracy Boulevard, Room 948, Bethesda, MD 20892, *GriederF@mail.nih.gov.* 301–435–0744.

Any interested person may file written comments with the committee by forwarding the 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.

Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/* where an agenda will be posted before the meeting date.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research