

**II. References**

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Kim, J., J. Gao, L. Amiri-Kordestani, et al., "Patient-Friendly Language to Facilitate Treatment Choice for Patients with Cancer." *The Oncologist*, 10.1634/theoncologist.2018-0761, 2019. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6693727/>.

2. Aikin, K.J., A.C. O'Donoghue, C.M. Squire, et al., "An Empirical Examination of the FDAAA-Mandated Toll-Free Statement for Consumer Reporting of Side Effects in Direct-to-Consumer Television Advertisements." *Journal of Public Policy & Marketing*, 35(1):108-123, 2016.

3. Sullivan, H.W., V. Boudewyns, A.C. O'Donoghue, et al., "Attention to and Distraction from Risk Information in Prescription Drug Advertising: An Eye-Tracking Study." *Journal of Public Policy & Marketing*, 36(2):236-245, 2017.

4. 21 U.S.C. 321(n).

Dated: January 23, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-01555 Filed 1-28-20; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0990-new]

**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 February 28, 2020.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-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 Collection:** Health Evaluation of Pregnancy Prevention Program Replications for High Risk and Hard to Reach Youth.

**Type of Collection:** OMB No. 0990-NEW.

**Abstract:** The Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), is requesting approval by OMB of a new information collection request. OASH seeks to collect information to understand whether previously proven adolescent pregnancy programs have similar effects on knowledge, attitudes, beliefs, intentions, and behaviors related to sexual activity and health among different youth in different locations, especially among understudied and hard-to-reach youth. We propose to collect both qualitative and quantitative information in a quasi-experimental design with a matched

comparison group. Eight organizations implementing a broad range of previously proven-effective pregnancy prevention programs (including sexual health education, sexual risk avoidance, and youth development programs) will recruit hard to reach or high-risk youth. Youth will complete surveys at baseline, immediately following the intervention, and at three months follow-up, yielding quantitative data about youth knowledge, attitudes, beliefs, intentions, and behaviors related to sexual health. Surveys will last for about 50 minutes. Focus groups yielding qualitative data about youth perspectives about adolescent pregnancy prevention programs will occur after the interventions are complete and will last for approximately 90 minutes.

**Need and Proposed Use of the Information:** Rates of pregnancy among hard-to-reach, high-risk, vulnerable, or understudied youth are significantly higher than the general population. However, there have been few evaluations assessing whether programs that have been previously proven successful can be delivered successfully to these youth. Hence, this evaluation is intended to help fill the evidence gap about the efficacy and effectiveness of existing pregnancy prevention programs among high-risk, vulnerable, or understudied youth. To enhance the rigor of the evaluation, a matched comparison group will be identified from select implementing organizations and their communities. OASH plans to use the findings of this evaluation to inform guidance to HHS grantees and prospective grantees on approaches for replication of pregnancy prevention programs for hard-to-reach and underserved youth.

**Likely respondents:** Respondents will include youth aged 12-16 years old, and their parents/guardians. Respondents will also include youth in a matched comparison group ("comparison youth").

**Burden:** Exhibit 1 summarizes the total annual burden hours estimated for this ICR. This hour-burden estimate includes time spent by program youth, comparison group youth, and parents/guardians of both groups to complete data collection for the ICR.

Respondents	Form name	Max number of respondents	Average burden per response (hours)	Total max burden (hours)
Youth Program Participants .....	Baseline survey and youth assent .....	1,216	1.00	1,216
	First follow-up survey .....	730	0.83	608
	3-month follow-up survey .....	438	0.83	365
	Focus group assent .....	474	0.25	119

Respondents	Form name	Max number of respondents	Average burden per response (hours)	Total max burden (hours)
Youth Comparison Group Participants .....	Focus group protocol .....	285	1.50	428
	Baseline survey and youth assent .....	2,946	1.00	2,946
	First follow-up survey .....	730	0.83	608
	3-month follow-up survey .....	438	0.83	365
Parents/Guardians .....	Parental consent .....	4,163	0.25	1,041
	Total .....			7,696

**Please Note:** No. Responses per Respondent is 1. Each form is completed one time.

**Terry Clark,**

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

[FR Doc. 2020-01573 Filed 1-28-20; 8:45 am]

**BILLING CODE 4150-34-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings 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.

The meetings will be closed to the public in accordance with the provisions set forth in section 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 Diabetes and Digestive and Kidney Diseases Advisory Council.

*Date:* May 12–13, 2020.

*Open:* May 12, 2020, 8:30 a.m. to 12:00 p.m.

*Agenda:* To Present the Director's Report and other Scientific Presentations.

*Place:* Porter Neuroscience Research Center, Building 35A, Conference Room 610-640, 35 Convent Drive, Bethesda, MD 20892.

*Closed:* May 12, 2020, 1:00 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Porter Neuroscience Research Center, Building 35A, Conference Room 610-640, 35 Convent Drive, Bethesda, MD 20892.

*Contact Person:* Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594-4757, [malikk@nidk.nih.gov](mailto:malikk@nidk.nih.gov).

*Name of Committee:* National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition.

*Date:* May 12–13, 2020.

*Open:* May 12, 2020, 1:00 p.m. to 2:00 p.m.

*Agenda:* To review the Division's scientific and planning activities.

*Place:* Porter Neuroscience Research Center, Building 35A, Conference Room 610-640, 35 Convent Drive, Bethesda, MD 20892.

*Closed:* May 12, 2020, 2:15 p.m. to 3:15 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Porter Neuroscience Research Center, Building 35A, Conference Room 610-640, 35 Convent Drive, Bethesda, MD 20892.

*Contact Person:* Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594-4757, [malikk@nidk.nih.gov](mailto:malikk@nidk.nih.gov).

*Name of Committee:* National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology, and Metabolic Diseases.

*Date:* May 12–13, 2020.

*Open:* May 12, 2020, 1:00 p.m. to 2:00 p.m.

*Agenda:* To review the Division's scientific and planning activities.

*Place:* Porter Neuroscience Research Center, Building 35A, Conference Room 610-640, 35 Convent Drive, Bethesda, MD 20892.

*Closed:* May 12, 2020, 2:15 p.m. to 3:45 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Porter Neuroscience Research Center, Building 35A, Conference Room 610-640, 35 Convent Drive, Bethesda, MD 20892.

*Contact Person:* Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy

Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594-4757, [malikk@nidk.nih.gov](mailto:malikk@nidk.nih.gov).

*Name of Committee:* National Diabetes and Digestive and Kidney Diseases Advisory Council; Kidney, Urologic, and Hematologic Diseases.

*Date:* May 12–13, 2020.

*Open:* May 12, 2020, 1:00 p.m. to 2:45 p.m.

*Agenda:* To review the Division's scientific and planning activities.

*Place:* Porter Neuroscience Research Center, Building 35A, Conference Room 610-640, 35 Convent Drive, Bethesda, MD 20892.

*Closed:* May 12, 2020, 2:45 p.m. to 3:45 p.m.

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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.

In the interest of security, NIH has stringent procedures for entrance into NIH federal property. 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: [www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm](http://www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)