

Division: Category A focuses on diabetes management and type 2 diabetes prevention; Category B focuses on CVD prevention and management. This information request package focuses on data collection activities for the Category A diabetes assessment.

This cooperative agreement is a substantial investment of federal funds. DDT and DHDSP are responsible for the stewardship of these funds, and they must be able to demonstrate the types of interventions being implemented and what is being accomplished through the use of these funds. Thus, throughout the five-year cooperative agreement period, CDC will work with HD recipients to track the implementation of the cooperative agreement strategies and evaluate program processes and outcomes. In order to collect this information for Category A, CDC has designed two overarching components: (1) Category A rapid evaluation of

DSMES and National DPP partner sites and (2) Category A recipient-led evaluations. Each component consists of data collection mechanisms and tools that are designed to capture the most relevant information needed to inform the evaluation effort while placing minimum burden on respondents. Respondents will include HD recipients, as well as select HD recipient partner sites, which are organizations that HD recipients are partnering with in the implementation of the 1815 strategies.

The evaluation of cooperative agreement strategies and activities conducted by DDT will determine the efficiency, effectiveness, impact and sustainability of 1815-funded strategies in the promotion, prevention, and management of diabetes and heart disease and help identify promising practices that can be replicated and scaled to better improve health outcomes. In addition, evaluation plays

a critical role in organizational learning, program planning, decision-making, and measurement of the 1815 strategies. As an action-oriented process, the evaluation will serve to identify programs that have positive outcomes, identify those that may need additional technical assistance support, and highlight the specific activities that make the biggest contribution to improving diabetes and cardiovascular disease prevention and management efforts. Without collection of new evaluative data, CDC will not be able to capture critical information needed to continuously improve programmatic efforts and clearly demonstrate the use of federal funds.

OMB approval is requested for three years. Participation is required for cooperative agreement awardees and voluntary for partner sites. The total estimated annualized burden hours are 1,084.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Department (1815 Recipient).	Evaluation and Performance Measurement Plan (EPMP)	17	1	8
	Recipient-Led Evaluation Reporting Template	51	1	8
	DSMES Partner Site-Level Rapid Evaluation Rapid Evaluation Form.	17	1	0.5
	National DPP Partner Site-Level Rapid Evaluation Nomination Form.	17	1	0.5
DSMES Partner Site	DSMES Partner Site-Level Rapid Evaluation Survey Questionnaire.	340	1	0.5
	Program Coordinator Interview Guide	14	1	2
	Professional Team Member Interview Guide	28	1	2
	Paraprofessional Team Member Interview Guide	28	1	2
National DPP Partner Site	National DPP Partner Site-Level Rapid Evaluation Survey Questionnaire.	340	1	0.5
	Program Coordinator Interview Guide	14	1	1
	Lifestyle Coach Interview Guide	28	1	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Head Start Act, notice is hereby given of three 1-day tribal consultation sessions to be held between HHS/ACF OHS leadership and the leadership of tribal governments operating Head Start and Early Head Start programs. The purpose of these consultation sessions is to discuss ways to better meet the needs of American Indian and Alaska Native (AIAN) children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. Three tribal consultations will be held as part of HHS/ACF or ACF Tribal Consultation Sessions. Please note the planned tribal consultation dates may be impacted by COVID-19 travel

restrictions. OHS will consider virtual means of facilitating tribal consultations and/or the postponing of tribal consultations should travel restrictions and group meeting limitations remain in effect.

DATES: July 9–10, 2020, 1 to 3 p.m.

July 14–16, 2020, 1 to 3 p.m.

Aug. 3, 2020, 1 to 5 p.m.

ADDRESSES:

- July 9–10, 2020—Glendale, AZ (Location TBD)
- July 14–16, 2020—Denver, CO (Location TBD)
- Aug. 3, 2020—Spokane, WA (Northern Quest Resort)

FOR FURTHER INFORMATION CONTACT:

Todd Lertjuntharangool, regional program manager, Region XI/AIAN, Office of Head Start, email

Todd.Lertjuntharangool@acf.hhs.gov, or phone (202) 205–9503. Additional information and online meeting registration will be available at <https://eclkc.ohs.acf.hhs.gov/about-us/article/2020-tribal-consultations>.

SUPPLEMENTARY INFORMATION: In accordance with Section 640(l)(4) of the Head Start Act, 42 U.S.C. 9835(1)(4), ACF announces OHS Tribal Consultation Sessions for leaders of tribal governments operating Head Start and Early Head Start programs. The agenda for the scheduled OHS tribal consultations in Glendale, Arizona; Spokane, Washington; and Denver, Colorado, will be organized around the statutory purposes related to meeting the needs of AIAN children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken, and in progress, to address the issues and concerns raised in the 2019 OHS Tribal Consultations.

The consultation sessions will be conducted with elected or appointed leaders of tribal governments and their designated representatives. Designees must have a letter from the tribal government authorizing them to represent the tribe. Tribal governments must submit the designee letter at least 3 days in advance of the consultation sessions to Todd Lertjuntharangool at Todd.Lertjuntharangool@acf.hhs.gov. Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each tribal consultation session will be prepared and made available within 45 days of the session to all tribal governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Todd Lertjuntharangool at Todd.Lertjuntharangool@acf.hhs.gov,

prior to each consultation session or within 30 days after each meeting.

OHS will summarize oral testimony and comments from the consultation sessions in each report without attribution, along with topics of concern and recommendations.

Megan E. Steel,

Executive Secretariat Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6085]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Administrative Practice and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 15, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0191. Also include

the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

General Administrative Practice and Procedures

OMB Control Number 0910–0191—Revision

This information collection supports FDA regulations governing its administrative practices and procedures. Although certain information collection pertaining to official administrative actions is not subject to review by OMB under the PRA in accordance with 44 U.S.C. 3518(c)(1)(B) (5 CFR 1320.4(a)(2)), we have reviewed our regulations and are revising this information collection to include provisions that we believe may be subject to OMB review. We are also revising the information collection to consolidate related activities discussed in Agency guidance, as we believe this will improve the efficiency of our operations.

In the **Federal Register** of January 9, 2020 (85 FR 1169), we published a 60-day notice soliciting comment on the proposed collection of information. Although two comments were received, neither was directly responsive to the information collection topics solicited. At the same time, the comments were supportive of FDA information collection activity, and we appreciate this input.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.19; request for waiver, suspension, or modification of requirements	1	1	1	1	1
10.30 and 10.31; citizen petitions and petitions related to ANDA, ² certain NDAs, ³ or certain BLAs ⁴	220	1	220	24	5,280
10.33; administrative reconsideration of action	6	1	6	10	60
10.35; administrative stay of action	5	1	5	10	50
10.65; meetings and correspondence	750	1	750	5	3,750
10.85; requests for Advisory opinions	4	1	4	16	64
10.115(f)(3); submitting draft guidance proposals	100	1	100	4	400