ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| AIAN Facility Survey | 155 | 3.5 | .1 | 54.25 |

*Estimated Total Annual Burden Hours:* 54.25.

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Authority:** 42 U.S.C 9846.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2019–11371 Filed 5–30–19; 8:45 am]

**BILLING CODE 4184–40–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Head Start Program Performance Standards (OMB #0970–0148)

**AGENCY:** Office of Head Start; Administration for Children and Families; HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Office Head Start (OHS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a three-year extension of the Head Start Program Performance Standards (HSPPS) information collection (OMB #0970–0148, expiration 1/31/2020). There are no changes requested to these record keeping requirements.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* This information collection was approved alongside the final rule for the revised HSPPS on September 1, 2016. This information collection is entirely record keeping and does not contain any standardized instruments or instructions. For example, this includes the requirement that programs maintain a waiting list of eligible families. There are no changes to the record keeping requirements contained in this information collection. Only minor adjustments were made to the estimated burden based on updated enrollment and staff data.

*Respondents:* Head Start grantees.

ANNUAL BURDEN ESTIMATES

| Record keeping requirement | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| 1301.6(a) | 3,020 | 1 | 0.70 | 2,114 |
| 1302.12(k) | 1,054,720 | 1 | .166 | 175,084 |
| 1302.14(c) | 3,020 | 1 | 2.00 | 6,040 |
| 1302.16(b) | 3,020 | 1 | 5.00 | 15,100 |
| 1302.33(a) and (b) | 1,054,720 | 1 | 1.00 | 1,054,720 |
| 1302.33(c)(2) | 294,632 | 1 | 2.00 | 589,264 |
| 1302.42(a) and (b) | 1,054,720 | 1 | 0.66 | 696,115 |
| 1302.42(e) | 3,020 | 1 | 0.50 | 1,510 |
| 1302.47(b)(7)(iv) | 3,020 | 1 | 0.50 | 1,510 |
| 1302.53 (b) & (d) | 3,020 | 1 | 0.166 | 501 |
| 1302.90(a) | 3,020 | 1 | 0.50 | 1,510 |
| 1302.90(b)(1)(i)–(iv),(b)(4) | 79,509 | 1 | 0.33 | 26,238 |
| 1302.93(a) | 26,503 | 1 | 0.25 | 6,626 |
| 1302.94(a) | 3,020 | 1 | 0.166 | 501 |
| 1302.101(a)(4)and 1302.102(b)–(c) | 3,020 | 1 | 79.00 | 238,580 |
| 1302.102(d)(3) | 110 | 1 | 10.00 | 1,100 |
| 1303.12 | 3,020 | 1 | 0.166 | 501 |
| 1303.22–24 | 956,120 | 1 | 0.33 | 315,520 |
| 1303.42–53 | 260 | 1 | 40.00 | 10,400 |
| 1303.70(c) | 200 | 1 | 1 | 200 |
| 1303.72(a)(3) | 3,020 | 1 | 2 | 6,040 |

*Estimated Total Annual Burden Hours:* 3,149,174.

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Authority:** 42 U.S.C. 9836A.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2019–11370 Filed 5–30–19; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–0001]**

### Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA, we) is announcing the following pubic workshop entitled ''Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations.'' This public workshop is convened by Duke University's Robert J. Margolis, MD, Center for Health Policy and supported by a cooperative agreement with FDA. The purpose of the public workshop is to capture stakeholder experiences with risk-based approaches to monitoring of clinical investigations and gather stakeholder input on opportunities to further the implementation of risk-based approaches to monitoring.

**DATES:** The public workshop will be held on July 17, 2019, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at the Marriott Marquis Washington, DC at 901 Massachusetts Ave. NW, in Washington DC. For additional travel and hotel information, please refer to the following website: *https://healthpolicy.duke.edu/events/improving-implementation-risk-based-monitoring-approaches-clinical-trials.* There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

**FOR FURTHER INFORMATION CONTACT:** Raymond Chiang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2232, Silver Spring, MD 20993, 301–796–1940, *Raymond.Chiang@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

To support greater implementation of risk-based approaches to monitoring (RBM) of clinical investigations, FDA issued draft guidance for industry in March 15, 2019 (84 FR 9531) entitled ''A Risk-Based Approach to Monitoring of Clinical Investigations: Questions and Answers, '' which is available at *https://www.fda.gov/media/121479/download.* This draft guidance expands on the guidance for industry entitled, ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' (August 2013) by providing additional guidance to facilitate sponsors' implementation of risk-based monitoring.

Traditionally, sponsors and research organizations have depended upon on-site monitoring and 100 percent source data verification for each clinical site, an approach that is resource intensive and may contribute to increased clinical trial costs. Adoption of RBM could lead to improvements to human subject protections, data integrity, and the efficiency of clinical investigations.

Data suggest that RBM has not yet been widely implemented. Therefore, FDA is seeking additional feedback from stakeholders on the challenges, barriers, and enablers that might be impacting the adoption of RBM. The public workshop addressed in this document is being held to capture stakeholder experiences with risk-based approaches to monitoring of clinical investigations and to gather stakeholder input on ways to improve the implementation of risk-based approaches to monitoring.

#### II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will cover a range of issues related to implementation of risk-based approaches to monitoring. Topics for discussion will include, and are not limited to, challenges to implementation of RBM, enablers to support implementation of RBM, and lessons learned from strategies employed to implement RBM.

#### III. Participating in the Public Workshop

*Registration:* To register for the public workshop, complete the registration form at *https://healthpolicy.duke.edu/events/improving-implementation-risk-based-monitoring-approaches-clinical-trials.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by July 16, 2019, by 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been registered. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact the Duke-Margolis Center for Health Policy (phone: 202–791–9561, email: *margolisevents@duke.edu*) no later than July 10, 2019.

*Streaming Webcast of the Public Workshop:* This public workshop will also be webcast and archived video footage will be available at the event website. Persons interested in viewing the live webcast are encouraged to register in advance (see *Registration*). The live webcast will also be available at the website above on the day of the event without preregistration. Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public workshop.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*Meeting Materials:* All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website: *https://healthpolicy.duke.edu/*