functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Awardee Lead Profile Assessment (ALPA) (OMB Control No. 0920–1215, Exp. 03/31/2024)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is requesting Paperwork Reduction Act (PRA) clearance for a three-year revised Information Collection Request (ICR) titled ''Awardee Lead Profile Assessment (ALPA)'' (OMB Control No. 0920–1215; Exp. 03/31/2024). The goal of this ICR is to build on the CDC's existing childhood lead poisoning prevention program. CDC requires that ongoing and new CDC Childhood Lead Poisoning Prevention Programs (CLPPPs), including the FY21 ''Childhood Lead Poisoning Prevention and Surveillance of Blood Lead Levels in Children'' (CDC–RFA–EH21–2102), complete the ALPA annually. This annual information collection will be used to identify jurisdictional legal frameworks governing CDC-funded CLPPPs in the United States and strategies for implementing childhood lead poisoning prevention activities. CDC can use this information to inform guidance, resource development, and technical assistance activities in support of the ultimate goal, which is eliminating lead exposure in children. The dissemination of these ALPA results will ensure that both funded and non-funded jurisdictions are able to: (1) identify policies and other factors that support or hinder childhood lead poisoning prevention efforts; (2) understand what strategies are being used by funded public health agencies to implement childhood lead poisoning prevention activities; and (3) use this knowledge to develop and apply similar strategies to support the national agenda to eliminate childhood lead poisoning. This program management information collection has been revised in several ways, including the addition of new answer options and questions to understand usage of the updated blood lead reference value (BLRV).

CDC will use one data collection mode, a web survey. A change in the mode of collection will not affect the total time burden requested as the time per response is the same for either mode, and the time to take the survey has remained consistent from 2021 estimates (47 minutes per response) despite revisions to the survey. This time estimate per response is based on pilot tests of the revised survey among eight respondents, and includes the time needed to review the ALPA Training Manual.

In total, the annual number of respondents remains unchanged at 75, and the annual time burden requested remains at 59 hours. There are no costs to respondents other than their time. The respondents are participating in this survey as a program requirement.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State or Local Governments (or their bona fide fiscal agents)	ALPA Web Survey	75	1	47/60

Jeffrey M. Zirger,

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

[FR Doc. 2023–06736 Filed 3–30–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–23DT; Docket No. CDC–2023–0022]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of Government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Reporting of the Essentials for Childhood (EfC): Preventing Adverse Childhood Experiences through Data to Action Program. This data collection will help to ensure that associated programs are

progressing toward achievement of their stated goals and objectives, as well as consistently demonstrating efficient and appropriate use of federal funds.

DATES: CDC must receive written comments on or before May 30, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0022 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Reporting of the Essentials for Childhood (EfC): Preventing Adverse Childhood Experiences through Data to Action Program—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this information collection effort is to collect Essentials for Childhood (EfC) program recipient data related to surveillance, implementation, program evaluation, and performance monitoring. This data collection is necessary to ensure that programs are progressing toward achievement of their stated goals and objectives, as well as consistently demonstrating efficient and appropriate use of federal funds. CDC will use the information collected to further understand the facilitators, barriers, and critical factors to implementing specific violence prevention strategies and conducting related program evaluation activities. Data collected will also be used to inform CDC's training and technical assistance, program improvement, and the development of future funding opportunities.

Data collection is designed to address the following key program evaluation questions:

- To what extent have recipients accomplished the short-term and intermediate-term outcomes outlined in the Logic Model?
- To what extent do recipients effectively implement ACEs prevention strategies during the period of performance?
- To what extent have recipients leveraged multi-sector partnerships and resources among state agencies (additional funding at the local level) and other sectors to prevent ACEs, including forming sustainable systems and partnerships, and realigning/focusing/mobilizing resources to prevent ACEs?
- In what ways has the recipient built or enhanced their state-level surveillance system to monitor ACEs, PCEs, and social determinants of health?
- How has the recipient integrated and addressed racial and health inequities and social determinants of health in preventing ACEs?
- To what extent have recipients enhanced their statewide action plan to implement complementary ACEs prevention strategies (additional funding for implementation at the local level)?
- To what extent have funded recipients enhanced their ability to use ACEs and PCEs surveillance and evaluation data to inform prevention strategy allocation?
- To what extent have recipients enhanced their ability to disseminate and use data to inform partner, policy, or other action?
- To what extent have recipients seen a sustainable increase in capacity and activities related to routine monitoring of ACEs and PCEs data among youth?
- To what extent have recipients seen a sustainable increase in capacity and activities related to routine monitoring of near real-time surveillance to monitor indicators of ACEs?
- To what extent have recipients demonstrated ability to link ACEs and PCEs data to those on the social determinants of health, and utilize these data to inform prevention strategies? (if applicable)
- What is the reach/exposure to the ACEs prevention program efforts?
- Are ACEs prevention strategies reaching populations at highest risk for ACEs?
- To what extent have recipients demonstrated use of surveillance and evaluation data to inform prevention strategy allocation and implementation to improve health equity?
- What has been the reach/exposure of ACEs and PCEs data dissemination efforts?

Information will be collected annually from recipients through the DVP Partners Portal, a web-based data collection system. The DVP Partners Portal allows recipients to fulfill their annual reporting obligations efficiently by employing user-friendly, easily accessible web-based instruments to collect necessary information for both progress reports and continuation applications. Because information from previous reports will be carried over and pre-populated for the next annual reporting, recipients will only need to enter changes, provide progress updates, and add any new information after the first year of reporting, which will help to reduce recipient burden.

CDC requests OMB approval for an estimated 552 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Essentials for Childhood (EfC) Grantees.	Annual Reporting—Project Leads	2	4	10	480
	Key Informant Interview—Principal Investigator	12	2	1	24
	Key Informant Interview—Principal Investigator/ Implementor.	12	2	1	24
	Surveillance Capacity Assessment—Surveillance Lead.	12	1	0.5	6
	Implementation Capacity Assessment	12	1	0.5	6
	Evaluation and Surveillance Survey—Surveillance Lead or Evaluator.	12	1	1	12
Total					552

Jeffrey M. Zirger,

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

[FR Doc. 2023–06738 Filed 3–30–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0142]

Research Involving Children as Subjects and Not Otherwise Approvable by an Institutional Review Board: Process for Referrals to Food and Drug Administration and Office for Human Research Protections, Guidance for Institutional Review Boards, Investigators, and Sponsors; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Research Involving Children as Subjects and Not Otherwise Approvable by an IRB: Process for Referrals to FDA and OHRP.'' This guidance is intended to assist institutional review boards (IRBs), institutions, investigators, and sponsors in understanding the processes used for review of research involving children as subjects that is not otherwise approvable by an IRB and has been referred to FDA, the Office for Human Research Protections (OHRP), or both, for review. When final, this guidance will replace the final guidance issued by FDA in December 2006 entitled, ''Guidance for Clinical Investigators, Institutional Review Boards and Sponsors: Process for Handing Referrals to FDA Under 21 CFR 50.54: Additional Safeguards for Children in Clinical Investigations'' and the guidance issued by the OHRP entitled ''Children as Research Subjects and the HHS '407' Process,'' issued on May 26, 2005. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by May 30, 2023 to ensure that the Agency and OHRP consider your comment on this draft guidance before they begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by May 30, 2023.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0142 for ''Research Involving Children as Subjects and Not Otherwise Approvable by an IRB: Process for Referrals to FDA and OHRP, Guidance for Institutional Review Boards, Investigators, and Sponsors.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your