

Attachment 8.ALPA Project Determination



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

Print Date: 2/23/23

Title: OMB 0920-1215 Awardee Lead Profile Assessment (ALPA)

Project Id: 0900f3eb81b58ce0

Accession #: NCEH-LPPEHTB-5/27/20-58ce0

Project Contact: Perri A Ruckart

Organization: NCEH/ATSDR/DEHSP/LPPEHTB

Status: **Project In Progress : PRA Revision**

Intended Use: **Project Determination**

Estimated Start Date: 06/01/2023

Estimated Completion Date: 05/31/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-1215

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(l)</i> Program Evaluation Quality Assurance / Improvement	12/7/22	Davis_Stephanie I. (sgd8) CIO HSC

PRA: PRA Applies		12/7/22	Davis_Stephanie I. (sgd8) CIO OMB / PRA
HRPO: Concur		6/29/20	Logan_Marinda D. (mwl8) HRPO Reviewer
ICRO: PRA Applies	OMB Approval date: 3/5/21 OMB Expiration date: 3/31/24	12/7/22	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard
Date Needed: 04/03/2023
Determination Start Date: 11/30/22

Description:

Submitting a 60 day FRN for a revision of a currently approved OMB protocol #0920-1215 (Expiration Date 03/31/2024). The purpose of this annual assessment under the cooperative agreement is to identify 1) jurisdictional legal frameworks governing CDC-funded childhood lead poisoning prevention programs (CLPPPs) in the United States and 2) strategies for implementing childhood lead poisoning prevention activities in the United States. Intended use of the resulting data: The information collection instrument 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. Assessment findings will be shared on the CDC CLPPP website; in response to inquiries by the public, press, and Congress; and a report or journal article may be published. The dissemination of results will support the ability for both funded and non-funded jurisdictions 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 state, territorial, and local governments (or their bona fide fiscal agents) 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.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The purpose of this annual assessment under the cooperative agreement is to identify 1) jurisdictional legal frameworks governing CDC-funded childhood lead poisoning prevention programs (CLPPPs) in the United States and 2) strategies for implementing childhood lead poisoning prevention activities in the United States.
Objective:	The results obtained from this survey will enable jurisdictions 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 state, territorial, and local governments (or their bona fide fiscal agents) 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.
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	Yes
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Yes
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Other - funded recipients (state and local health departments)
Tags/Keywords:	Lead Poisoning
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
Method Categories:	Survey
Methods:	Each recipient has one project manager for lead poisoning prevention activities. Each project manager will complete the questionnaire in his or her official capacity. The ALPA questionnaire will use the EpiInfo functionality as the primary method for respondents to complete the information. The link will be sent via an invitation email by a CDC staff member to the attention of all project managers of the funded programs approximately 150 days before the end of the annual budget period. A follow-up email will be sent to the attention of all project managers approximately 130 days before the end of the annual budget period.
Collection of Info, Data or Biospecimen:	Data will be collected electronically using a web-based link to an Epi Info 7TM survey (Attachment 4). This method was chosen to reduce the overall burden on respondents and do not require any special technical expertise or proprietary software. The survey instrument was designed to collect the minimum information necessary for the purpose of this information collection.

Expected Use of Findings/Results and their impact:

The results obtained from this survey will enable jurisdictions 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 state, territorial, and local governments (or their bona fide fiscal agents) 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. Both funded and non-funded jurisdictions will be able to apply these principles to their childhood lead poisoning prevention programs. Findings will be shared on CDC's CLPPP website, in response to inquiries by the public, press, and Congress, and a report or journal article may be published.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Childhood Lead Poisoning Prevention and Surveillance of Blood Lead Levels in Children	CDC-RFA-EH21-2102	2021	5	
CDC Cooperative Agreement	Lead Poisoning Prevention- Childhood Lead Poisoning Prevention	CDC-RFA-EH17-1701PPHF17	2017	4	
CDC Cooperative Agreement	Childhood Lead Poisoning Prevention Projects, State and Local Childhood Lead Poisoning Prevention and Surveillance of Blood Lead Levels in Children	CDC-RFA-EH18-1806	2018	3	

HSC Review

HSC Attributes

Program Evaluation Yes

Quality Assurance / Improvement Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office ☐ No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

Population - Emancipated Minors

Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

Informed consent for adults ☐ No Selection

Children capable of providing assent ☐ No Selection

Parental permission ☐ No Selection

Alteration of authorization under HIPPA Privacy Rule ☐ No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults ☐ No Selection

Children capable of providing assent ☐ No Selection

Parental permission ☐ No Selection

Consent process shown in an understandable language

Reading level has been estimated ☐ No Selection

Comprehension tool is provided ☐ No Selection

Short form is provided ☐ No Selection

Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identifiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added

Staff

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Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Kelly Dyke	12/17 /2023				Data Owner	nfn8@cdc.gov	404-498-1215	PROGRAM SERVICES
Perri Ruckart	03/15 /2024	08/13/2023	08/14/2023		Program Official	afp4@cdc.gov	770-488-3808	LEAD POISONING PREVENTION AND ENVIRONMENTAL HEALTH TRACKING BRANCH
Rio Schondelmeyer	05/27 /2023				Data Use Contact	prw8@cdc.gov	404-498-2797	PROGRAM DEVELOPMENT, COMMUNICATIONS AND EVALUATION

Data

DMP

Proposed Data Collection Start Date: 6/1/21

Proposed Data Collection End Date: 5/31/24

Proposed Public Access Level: Public, Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact:

Public Access Justification: De-identified data can be shared. Data will be shared in aggregate form.

How Access Will Be Provided for Data: ALPA data will be on CDC servers and access will be limited to CDC project staff who has PIV cards. The ALPA will not involve the collection of personally identifiable or sensitive information. The ALPA involves collection of data regarding childhood lead poisoning prevention programs (#entities#) and not persons. Aggregate data will be publicly available on CDC CLPPP website and additional data may be shared upon request for approved purposes via data use agreement

Plans for Archival and Long Term Preservation:

Spatiality

Spatiality (Geographic Locations) yet to be added

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	12/07/2022	NOA 0920-1215 (2021)	Notice of Action	NOA 0920-1215_2021.pdf
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	12/07/2022	ALPA 60-day FRN request package	Paperwork Reduction Act Form	ALPA 60D for ICRO 20221207.zip
	Ruckart_Perri A. (afp4) Project Contact	12/06/2022	files revised in response to comments	Paperwork Reduction Act Form	Revised files for 60D.zip
	Davis_Stephanie I. (sgd8) CIO HSC	12/06/2022	ALPA 60-day draft package with OS comments	Paperwork Reduction Act Form	Files rev OS.zip
	Ruckart_Perri A. (afp4) Branch Approver Projects	12/02/2022	documents required for 60D FRN	Paperwork Reduction Act Form	draft ALPA 60D Dec 2 2022.zip
	Ruckart_Perri A. (afp4)	11/30/2022	draft documents for ALPA revision	Paperwork Reduction Act Form	draft ALPA revision 2022.zip

	Project Contact		2022		
	Zirger_Jeffrey (wtj5) ICRO Reviewer	05/31/2022	NOA 0920-1215 (2021)	Notice of Action	NOA 0920-1215_2021.pdf
	Davis_Stephanie I. (sgd8) CIO HSC	05/27/2022	Change Request documents ready for ICRO	Paperwork Reduction Act Form	0920-1215 ChngRqst to ICRO 20220527.zip
	Schondelmeyer_Rio (prw8) Project Contact	05/26/2022	Clean Version of Revised Attachment 4c	Other	Att4c ALPA Training Manual_clean.docx
	Schondelmeyer_Rio (prw8) Project Contact	05/26/2022	Justification for non-substantive change request	Other	0920-1215 ALPA Nonmaterial Change Justification. docx
	Schondelmeyer_Rio (prw8) Project Contact	05/26/2022	Attachment 4c with track changes	Other	Att4c ALPA Training Manual_track changes.docx
	Schondelmeyer_Rio (prw8) Project Contact	05/26/2022	Clean Version of Revised Attachment 4b	Other	Att4b ALPA_clean.docx
	Schondelmeyer_Rio (prw8) Project Contact	05/26/2022	Attachment 4b with track changes	Other	Att4b ALPA_track changes.docx
	Zirger_Jeffrey (wtj5) ICRO Reviewer	08/30/2021	NOA 0920-1215	Notice of Action	NOA 0920-1215_2021.pdf
	Schondelmeyer_Rio (prw8) CIO HSC	08/27/2021	Track changes file	Other	0920-1215 ALPA Changes.zip
	Schondelmeyer_Rio (prw8) CIO HSC	08/27/2021	No changes were made to this file.	Other	0920-1215 ALPA Change Request Justification 20200928 (1).docx
	Schondelmeyer_Rio (prw8) CIO HSC	08/27/2021	Documents without any changes.	Other	0920-1215 ALPA No Changes.zip
	Davis_Stephanie I. (sgd8) CIO HSC	08/27/2021	ALPA Change Request Justification	Other	0920-1215 ALPA Change Request Justification 20200928.docx
	Davis_Stephanie I.		ALPA ICR Files - changes (to be		

	(sgd8) CIO HSC	08/27/2021	reviewed by ICRO and OMB)	Paperwork Reduction Act Form	0920-1215 ALPA Changes.zip
	Davis_Stephanie I. (sgd8) CIO HSC	08/27/2021	ALPA ICR Files - no changes (does not need review by ICRO or OMB)	Paperwork Reduction Act Form	0920-1215 ALPA No Changes.zip
	Schondelmeyer_Rio (prw8) CIO HSC	08/27/2021	Track change and clean copies are included for each document in the package.	0.1255X Request for Exemption or Review of Changes	Simple Change Request.zip
	Ruckart_Perri A. (afp4) CIO HSC	09/29/2020	revised as requested	Other	Att4a ALPA Web Survey.docx
	Ruckart_Perri A. (afp4) Project Contact	09/24/2020	30 day FRN package documents	Other	0920-1215 ALPA revision for 30D prep.zip
	Ruckart_Perri A. (afp4) Project Contact	09/22/2020	information/documents needed for 30 day package	Other	0920-1215 ALPA revision for 30D prep.zip
	Davis_Stephanie I. (sgd8) CIO HSC	06/26/2020	60D ALPA zipfile ready for ICRO	Other	OMB ALPA 2021 revision to ICRO 20200626.zip
	Ruckart_Perri A. (afp4) Project Contact	06/26/2020	changes made as requested by OS	Other	OMB ALPA 2021 revision 6-26-20.zip
	Davis_Stephanie I. (sgd8) CIO HSC	06/25/2020	zip file 60D ICR OS rev	Other	OMB ALPA 2021 revision rev OS.zip
	Ruckart_Perri A. (afp4) Project Contact	06/23/2020	revised as requested	Other	OMB ALPA 2021 revision.zip
	Davis_Stephanie I. (sgd8) CIO HSC	06/18/2020	2021 ALPA 60D FRN and package	Other	2021 ALPA 60D rev OS.zip
	Ruckart_Perri A. (afp4) Project Contact	06/12/2020	zip file including documents necessary for OMB package revision	Other	OMB ALPA 2021 Revision.zip
	Ruckart_Perri A. (afp4) Project Contact	06/02/2020	OMB approval or previous survey that is the basis for this revision.	Other	0920-1215-17ADS ALPA 09FEB2018_APPROVAL.pdf



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