



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

Print Date: 9/29/20

Title: Blood Lead Surveillance System (BLSS) -- OMB No. 0920-0931

Project Id: 0900f3eb81bcf99b

Accession #: NCEH-LPPEHTB-8/31/20-cf99b

Project Contact: Courtney_Joseph (hzc2)

Organization: NCEH/ATSDR/DEHSP/LPPEHTB

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 08/31/2020

Estimated Completion Date: 09/30/2020

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-0931

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(l)(2)</i>	9/29/20	Lawler_Tameka (giq3) CIO HSC
PRA: PRA Applies		9/29/20	Lawler_Tameka (giq3) CIO OMB / PRA

Description & Funding

Description

Priority: Standard

Date Needed: 09/30/2020

Determination Start Date: 09/02/20

Description: This CDC information collection request (ICR) includes two data collection systems that provide a coordinated, comprehensive, and systematic public health approach to the surveillance and monitoring of blood lead levels (BLLs) for children and occupationally exposed adults in the U.S. We are requesting an extension for the current OMB approval which expires on May 31, 2021 (# 0920-0931).

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

IMS Activation Name: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose We are requesting an extension for the current OMB approval for BLSS which expires on May 31, 2021.

Objective: The overarching goal of this information collection is to continue the blood lead surveillance collection for children and occupationally-exposed adults in the U.S.

Activities or Tasks: Secondary Data or Specimen Analysis

Target Populations to be Included/Represented: Children, Other

Tags/Keywords: Lead Poisoning, Nervous System, Childhood, Lead Poisoning, Nervous System, Adult, Public Health Surveillance

CDC's Role: CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens, CDC employees will provide substantial technical assistance or oversight, CDC is providing funding

Method Categories: Surveillance Support

Methods: State and local health departments submit standardized Childhood Blood Lead Surveillance (CBLS) data on a quarterly basis via the CDC's Secure Access Management System's (SAMS) Secure Data eXchange's (SDX) integrated Managed File Transfer (MFT) Platform. CDC staff import and store the CBLS data on a secure CDC network drive for processing, analysis, and generation of reports. State health and labor departments submit Adult Blood Lead Epidemiology and Surveillance (ABLES) data on an annual basis through secure encrypted FTP sites. ABLES data are stored on secure CDC network drives for processing, analysis, and generation of reports.

CDC does not collect these data directly, they are submitted by the states and local programs as described in the Methods above. CBLS collects all laboratory and clinician-reported blood lead levels (BLLs) test results on individual children reported to participating state or local CLPPPs. The de-identified, individual-level case management and follow-up data are forwarded to CDC,

Collection of Info, Data or Biospecimen:

imported into CBLS, and a consistent #case# definition is then applied. The Adult Blood Lead Epidemiology and Surveillance (ABLES) program, a part of CDC's NIOSH, compiles state surveillance data for adults 16 years of age or greater, most of whom are occupationally exposed.

Expected Use of Findings/Results:

Data generated and analyzed from these two programs provide critical information to monitor trends in BLLs over time. This information is used for program implementation, policy development, and to target population-based interventions to children at high risk for lead exposure and adults who may be exposed to lead in the workplace.

Could Individuals potentially be identified based on Information Collected? Yes

Will PII be captured (including coded data)? Yes

Does CDC have access to the identifiers? No

Is an assurance of confidentiality in place or planned? No

Is a certificate of confidentiality in place or planned? No

Is there a formal written agreement prohibiting the release of identifiers? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
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 SUPP20	2018	1
CDC Cooperative Agreement	Lead Poisoning Prevention-Childhood Lead Poisoning Prevention	CDC-RFA-EH17-1701SUPP20	2017	1

HSC Review

Regulation and Policy

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

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

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 documents 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

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
Benjamin	03/18				Technical	yhp5@cdc.	770-488-	OFFICE OF FINANCIAL INFORMATION SYSTEMS

Bina	/2023				Monitor	gov	2093	
David Wall	12/18 /2022				Technical Monitor	dkw0@cdc. gov	513- 841- 4331	HEALTH INFORMATICS BRANCH
John Lu	08/17 /2023		11/07/2021		Technical Monitor	czl5@cdc. gov	513- 841-5	HEALTH INFORMATICS BRANCH
Joseph Courtney	08/31 /2023				Program Lead	hzc2@cdc. gov	404- 498- 3282	LEAD POISONING PREVENTION AND ENVIRONMENTAL HEALTH TRACKING BRANCH
KATHRYN EGAN	03/25 /2022				Technical Monitor	nky9@cdc. gov	404- 718- 5778	EPIDIMIOLOGY AND SURVEILLANCE
Marie Haring Sweeney	11/22 /2022	11/30/2021			Program Lead	mhs2@cdc. gov	513- 841- 4102	HEALTH INFORMATICS BRANCH
Monica Leonard	08/31 /2023				Program Lead	zgf7@cdc. gov	404- 498- 1826	DIVISION OF ENVIRONMENTAL HEALTH SCIENCE AND PRACTICE
Qaiyim Harris	06/09 /2023				Technical Monitor	qah3@cdc. gov	770- 488- 7115	EPIDIMIOLOGY AND SURVEILLANCE
Rebecca Tsai	12/14 /2021		12/16/2022		Technical Monitor	vht5@cdc. gov	513- 841- 4398	HEALTH INFORMATICS BRANCH
Scott Henn	03/04 /2022	11/06/2021			Technical Monitor	ajn4@cdc. gov	513- 841- 4173	HEALTH INFORMATICS BRANCH
Stella Chuke	08/31 /2023				Technical Monitor	slc7@cdc. gov	770- 488- 3475	EPIDIMIOLOGY AND SURVEILLANCE

Data

DMP

Proposed Data Collection Start Date: 6/1/21
Proposed Data Collection End Date: 5/31/24
Proposed Public Access Level: Public

Public Access Justification: This is a publicly funded program to help state and local programs collect important data. Sharing the aggregate data with the public is an important part of the process.

How Access Will Be Provided for Data: Both the CBLS and ABLES data will be disseminated on program websites and in MMWR Surveillance Reports. Because CBLS datasets include some required variables with potentially personally identifiable information (PII) (e.g., age, race, sex, county of address) which may present privacy concerns due to small numbers for some of the variables, small cell sizes (counts <5) will be redacted from all datasets or summary tables that are disseminated in any way.

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...									

