



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:<br>Does NOT Require HRPO<br>Review | Not Research - Public Health Surveillance<br><i>45 CFR 46.102(l)(2)</i> | 9/29/20   | Lawler_Tameka (giq3) CIO HSC       |
| PRA:<br>PRA Applies                     |   | 9/29/20   | Lawler_Tameka (giq3) CIO OMB / PRA |

## Description & Funding

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### 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**

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**Regulation and Policy**

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**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

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

## Data

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### 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... |                     |                       |                     |                             |                     |              |                       |                       |                     |

