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

Print Date: 5/19/25

Title:	ATSDR Exposure Investigations Generic Clearance PRA Revision 1
Project Id:	0900f3eb82456d90
Accession #:	NCEH-OCHHA-7/29/21-8f334
Project Contact:	Karen M Scruton
Organization:	NCEH/ATSDR/OCHHA
Status:	**Pending Regulatory Clearance : PRA Revision**
Intended Use:	**Project Determination**
Estimated Start Date:	10/01/2024
Estimated Completion Date:	12/31/2025
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0923-0048 (exp 06/30/2025)

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	10/23/24	Ding_Yan (Shirley) (yad6) CIO HSC
PRA: **PRA Applies**		10/23/24	Ding_Yan (Shirley) (yad6) CIO OMB / PRA
ICRO: **PRA Applies**	OMB Approval date: 6/15/22 OMB Expiration date: 6/30/25	10/23/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Priority Justification:

CDC Priority Area for this Project: Other CDC Priority - Exposure Investigations GenIC package

Determination Start Date: 09/30/24

Description: This is an extension of an existing Information Collection Request for Exposure Investigations. OMB Control Number 0923-0048 (exp 06/30/2025). This is a request to publish the 60-day Federal Register Notice (FRN).

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

IMS Activation Name: Not selected

Submitted through IMS Clearance Matrix: Not selected

Primary Scientific Priority: Not selected

Secondary Scientific Priority (s): Not selected

Task Force Responsible: 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 To allow a mechanism for expedited clearance of OMB packages for Exposure Investigations.

Objective:	To extend OMB approval of the Generic Information Collection package for Exposure Investigations
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Environmental Exposure
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:	Exposure Investigation
Methods:	ATSDR will conduct exposure investigations at sites where the agency criteria for conducting exposure investigations are met.
Collection of Info, Data or Biospecimen:	Biological or environmental samples, or both, using convenience sampling, and questionnaire data will be collected at sites that meet agency criteria for conducting exposure investigations.
Expected Use of Findings/Results and their impact:	The data generated from the exposure investigation will be used to assist ATSDR in making recommendations to reduce environmental exposure within communities. The data may be shared with local, state or federal environmental agencies as appropriate.
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 (including coded data)?:	Yes
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
Other-EI may be funded via various mechanisms	Pending				0.00

HSC Review

Regulation and Policy

Do you anticipate this project will require review by a CDC IRB or HRPO? 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 waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPAA 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 identfiable 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

Will you be working with an outside Organization or Institution? No

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	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Karen Scruton	08/04 /2026	05/01/2017	11/10/2024			Principal Investigator	isg3@cdc.gov	770-488-1325	OFFICE OF COMMUNITY HEALTH AND HAZARD ASSESSMENT

Data

DMP

Proposed Data Collection Start Date:	7/29/21
Proposed Data Collection End Date:	7/29/25
Proposed Public Access Level:	Public, Non-Public

Non-Public Details:

Reason For Not Releasing Data:	Other - Data may have PII - may be shared with other environmental or public health agencies per the consent form.
Public Access Justification:	The public will be provided the results of the exposure investigations biological testing and/or environmental sampling in a summary form. Detailed data may be shared with environmental and public health agencies per the consent form agreement.
How Access Will Be Provided for Data:	Data will be managed per ATSDR requirements for PII. Data may be shared with other environmental and public health agencies if stipulated in the consent form.
Plans for Archival and Long Term Preservation:	The data will be retained per federal retention standards.

Spatiality

Country	State/Province	County/Region
Virgin Islands of the United States		
United States		

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

No Supporting Info

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