



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

Print Date: 12/10/21

Title: ATSDR Exposure Investigations Generic Clearance

Project Id: 0900f3eb81d8f334

Accession #: NCEH-OCHHA-7/29/21-8f334

Project Contact: Karen M Scruton

Organization: NCEH/ATSDR/OCHHA

Status: **Pending Clearance : PRA Revision**

Intended Use: **Project Determination**

Estimated Start Date: 07/29/2021

Estimated Completion Date: 07/29/2025

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0923-0048 (exp 04/30/2022)

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>	7/30/21	Davis_Stephanie I. (sgd8) CIO HSC
PRA: PRA Applies		7/30/21	Davis_Stephanie I. (sgd8) CIO OMB / PRA

ICRO:
PRA Applies

OMB Approval date: 4/16/19
OMB Expiration date: 4/30/22

8/2/21

Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Determination Start Date:	12/09/21
Description:	This is an extension of an existing Information Collection Request for Exposure Investigations. OMB Control Number 0923-0048 (exp 04/30/2022). This is a request to publish the 60-day Federal Register Notice (FRN).
IMS/CIO/Epi-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
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 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?:	No
Project does not incorporate elements of health equity science:	Yes
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Not Selected
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: 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 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 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

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...									



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