



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

Print Date: 9/11/24

Title:	Assessment of Chemical Exposures (ACE) Investigations (OMB No.09230051)
Project Id:	0900f3eb81b8c0ed
Accession #:	NCEH-EHSB-7/9/20-8c0ed
Project Contact:	Maureen F Orr
Organization:	NCEH/ATSDR/DTHHS/EHSB
Status:	Project In Progress
Intended Use:	Project Determination
Estimated Start Date:	03/31/2021
Estimated Completion Date:	03/31/2024
CDC/ATSDR HRPO/IRB Protocol #:	n/a
OMB Control #:	09230051

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>	6/7/24	Ding_Yan (Shirley) (yad6) CIO HSC
PRA: PRA Applies		6/7/24	Ding_Yan (Shirley) (yad6) CIO OMB / PRA
ICRO: PRA Applies	OMB Approval date: 10/25/21 OMB Expiration date: 10/31/24	6/10/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 07/23/2020

Priority Justification:

CDC Priority Area for this Project: Not selected

Determination Start Date: 07/21/20

Description: ATSDR is requesting a continuation of the OMB Gen IC for the Assessment of Chemical Exposures (ACE) investigations (OMB No. 09230051) for an additional 3 years. The ACE toolkit is a modifiable set of surveys and databases used to conduct an epidemiologic assessment after a chemical incident. The existing surveys have been shortened and field data entry will be implemented. The part of the toolkit formerly the ACE short form has been renamed Epidemiologic Contact Assessment Symptom Exposure (Epi CASE). We would like to expand the collection to include not just chemical incidents but working with our partners (NCEH and NIOSH) include a broader range of environmental incidents including nuclear, radiological, natural disasters, and explosions. Due to this there will be an increase in requested burden hours of 180.3.

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	The ACE program helps state and local health departments conduct an epidemiologic assessment after an environmental exposure incident.
Objective:	Generally these are the objectives, each state/local health department sets their own. To better understand the impact of an environmental incident on the community and make recommendations to fulfil their needs. To assess the public health response and impact of the incident and make recommendations to improve. To understand the cause of the incident and make recommendations to prevent similar incidents from happening. To define a group of individuals who may need follow up for potential mental and physical health effects in the future.
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	Not Selected
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	Not Selected
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Disasters
CDC's Role:	Activity originated and designed by non-CDC staff (awardee or external collaborator) ; CDC employees or agents will obtain data by intervening or interacting with participants ; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s) ; CDC employees will provide substantial technical assistance or oversight ; CDC is NOT a recipient or provider of private data, specimens, materials or services ; CDC is provider of technical assistance or staff time in the absence of CDC support
Method Categories:	Exposure Investigation; Individual Interview (Quantitative); Record Review
Methods:	The ACE toolkit contains modifiable individual as well as household level surveys. It contains a survey for the hospital staff as well as medical chart abstraction forms. There are epi info databases to enter and analyze the data. WE are developing filed data entry screens. Most data analysis are descriptive. GIS modeling is often used to try to identify the area of exposure. I have listed exposure investigation, but it is not the traditional ATSDR Exposure investigation (EI). Surveys are usually collected door to door in an affected community. If the size of the affected community is large and the time to collect the data are limited, sampling may be employed using the CASPER model. GRASP generally assists us to identify the affected area to interview. Surveys of responders or workers are generally conducted at their workplace. If we are unable to do in
Collection of Info, Data or Biospecimen:	

person interview, phone interviews may be done to catch those we were unable to interview in person. we consult with the NCEH labs and toxicologists to determine if we should consider biomonitoring. If it is indicated, then we will work with the NCEH labs to collect and test specimens.

Expected Use of Findings/Results and their impact:

Data are used to help the community. It will determine any resources they may need, to improve the communities emergency response procedures and prevent future similar incidents. Results are often published in the MMWR or other journals.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
Technical assist-CDC not reimbursed	EPI Aid				

HSC Review

Additional Ethical Considerations

The ACE Investigations are public health surveillance activities designed to assess population exposures to chemical releases in affected communities, and at the request of the state or local public health agency.

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 wavers

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 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

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
Maureen Orr	06/05 /2026		01/13/2025			Program Lead	mco0@cdc.gov	770-488-3806	ENVIRONMENTAL HEALTH SURVEILLANCE BRANCH

Data

DMP

Proposed Data Collection Start Date: 3/31/21
Proposed Data Collection End Date: 3/31/24
Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Country/Jurisdiction owns the data with protections under their laws and regulations
Public Access Justification: CDC/ATSDR does not own the data, it is the state or county who requested the ACE assistance.
How Access Will Be Provided for Data: this is up to the states regulations.
Plans for Archival and Long Term Preservation: this is up to the states regulations.

Spatiality

Country	State/Province	County/Region
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

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	06/10/2024	NOA 0923-0051 (2021)	Notice of Action	NOA 0923-0051_2021.pdf
Current	Orr_Maureen F. (mco0) Project Contact	06/06/2024	60D ICR package to submit to ICRO for public comment	Other	20200812 ACE 60D FRN to ICRO.zip
Current	Orr_Maureen F. (mco0) Project Contact	06/06/2024	checklist for 60 day notice -I could not open the one on sharedrive.	Paperwork Reduction Act Form	Att2 ACE 60D FRN Request Form 20240603.pdf
Current	Orr_Maureen F. (mco0) Project Contact	06/06/2024	60 day OMB package for ACE	Paperwork Reduction Act Form	OneDrive_1_6-6-2024.zip
	Davis_Stephanie I. (sgd8) CIO HSC	08/12/2020	60D ICR package to submit to ICRO for public comment	Other	20200812 ACE 60D FRN to ICRO.zip
	Orr_Maureen F. (mco0) Project Contact	08/12/2020	zipped revised materials. Please note that I changed the order, Epi CASE is appendix D and General Survey is Appendix E. Also Att 8 was added- the Epi CASE just in time training manual so ATT 9 is now the RD and 10 the Rash report. There was an MMWR published on the Virgin islands ACE, I can make that 10 if you like.	Paperwork Reduction Act Form	Att10 ACE Rash Report.zip
	Davis_Stephanie I. (sgd8) CIO HSC	07/31/2020	Current FRN Publication Request Worksheet. Please use this one	Paperwork Reduction Act Form	FRN_Publication_Request_Worksheet.pdf
	Davis_Stephanie I. (sgd8) CIO HSC	07/31/2020	Zipfile of draft 60D PRA ICR reviewed as of 07/31/2020	Other	OS rev 20200730.zip
	Orr_Maureen F. (mco0) Project Contact	07/21/2020	60 day OMB renewal package for 09230051 Assessment of Chemical Exposures	Paperwork Reduction Act Form	2021 renew 0923-0051.zip



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