

Attachment 6. ACE Research Determination



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

Print Date: 8/12/20

Title: Assessment of Chemical Exposures (ACE) Investigations (OMB No.09230051)

Project Id: 0900f3eb81b8c0ed

Accession #: NCEH-EHSB-7/9/20-8c0ed

Project Contact: Orr_Maureen F. (mco0)

Organization: NCEH/ATSDR/DTHHS/EHSB

Status: **Pending Regulatory Clearance**

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(l)(2)</i>	8/12/20	Davis_Stephanie I. (sgd8) CIO HSC
PRA: PRA Applies		8/12/20	Davis_Stephanie I. (sgd8) CIO OMB / PRA

Description & Funding

Description

Priority: Standard

Date Needed: 07/23/2020

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/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 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.

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).

Collection of Info, Data or Biospecimen:

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 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:

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
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 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
Maureen Orr	02/28/2023		01/16/2022		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...									



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