Print Date: 5/25/21



Title: Focus Groups with Communities Concerned about Excess Cancer and Environmental Hazards

0900f3eb81d2edb4 Project Id: NCEH-HST-5/18/21-2edb4 Accession #:

**Project Contact:** Amy Lavery

NCEH/ATSDR/DEHSP/EMRCB/HST Organization:

Status: **Pending Clearance Project Determination** Intended Use:

**Estimated Start Date:** 09/01/2021 **Estimated Completion Date:** 12/31/2022 CDC/ATSDR HRPO/IRB Protocol #: N/A OMB Control #: TRA

## **Determinations**

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other  45 CFR 46.102(I)  Other - Designed to improve communications strategies for Cancer Cluster Guidelines update	5/25/21	Davis_Stephanie I. (sgd8) CIO HSC
PRA: PRA Applies		5/25/21	Davis_Stephanie I. (sgd8) CIO OMB / PRA

# **Description & Funding**

### Description

**Priority:** Urgent Date Needed: 05/21/2021

**Priority Justification:** This project was submitted to OMB for project review and undergoing an expedited review to try to meet overall

project timelines.

**Determination Start Date:** 05/18/21

Description: In September 2013, NCEH/ATSDR and the Council of State and Territorial Epidemiologists (CSTE) published

guidelines in the Morbidity and Mortality Weekly Report titled Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists (hereafter referred to as the "2013 Guidelines"). The 2013 Guidelines are a tool to assist STLT public health  $agencies \ in \ applying \ a \ systematic \ approach \ when \ responding \ to \ inquiries \ about \ suspected \ cancer \ clusters \ in$ residential or community settings. NCEH and ATSDR are updating the 2013 Guidelines to ensure STLT public health agencies and stakeholders have access to information about current scientific tools and approaches to assess and respond to potential cancer clusters, or excess cancer, in communities. The update to the 2013 Guidelines will be informed by a multitude of inputs including stakeholders, subject matter experts, STLT public health agencies, and the public. As part of the process to update the 2013 Guidelines, NCEH/ATSDR is interested in identifying and developing additional communications-related strategies, guidance, resources, and tools. NCEH/ATSDR would like to obtain input from community members and advocates to understand how they have typically been involved in activities associated with understanding concerns about excess cancer and environmental hazards. The information collected will allow NCEH/ATSDR to gain an understanding of what has worked well (and what has not worked well) with this process in the past and obtain communities' suggestions to create more effective communication

strategies to support those efforts in the future No

IMS/CIO/Epi-Aid/Chemical Exposure

Submission:

**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 The goal of this project is to assess affected communities' experiences engaging with federal, state, tribal, local,

and territorial public health agencies responding to concerns about excess cancer.

Objective: The information collected will be used to understand what has and has not worked well with cancer cluster

investigation processes in the past and to obtain suggestions to create more effective communication strategies to

support those efforts in the future.

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?:

Project does not incorporate elements of

health equity science:

Not Selected

Not Selected

Not Selected Measuring Disparities: **Studying Social Determinants of Health** Not Selected (SDOH):

Assessing Impact: Methods to Improve Health Equity Research Yes

and Practice:

Other: Not Selected

**Activities or Tasks:** New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented:

General US Population

Tags/Keywords: Communication; Communication Barriers; Community Participation; Focus Groups

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; CDC employees or agents will obtain or use anonymous or unlinked 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

providing funding

**Method Categories:** Focus Group

The administration of focus groups will be conducted by a contractor (ICF). Each focus group comprises community

members and advocates who have been involved in or aware of cancer cluster concerns or investigations in their communities. Some key informant interviews may be conducted, as well. Data will be analyzed using qualitative

methods, specifically thematic analysis to extract themes among participant responses.

Collection of Info, Data or Biospecimen: Data will be collected through a series of focus groups (up to 12) that will last approximately 90 minutes each.

Expected Use of Findings/Results: Results from the focus groups will be used to inform the development of communications-related strategies.

quidance, resources, and tools that state, tribal, local, and territorial public health partners may use when

responding to community concerns about excess cancer and environmental hazards.

Could Individuals potentially be identified

based on Information Collected?

# **Funding**

F	Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
(	CDC Contract	ENHANCED CANCER CLUSTER COMMUNICATIONS	1202044124	2020	1	107574.00

# **HSC Review**

# **HSC Attributes**

Other - Designed to improve communications strategies for Cancer Cluster Guidelines update

Yes

# **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 waviers

Informed consent for adults

No Selection

Children capable of providing assent

No Selection

No Selection

Alteration of authorization under HIPPA

Privacy Rule

## **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)

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

Human genetic testing is planned now or in the future

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

# **Institutions & Staff**

#### **Institutions**

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
ICF Inc. and Subsidiary Organizations	FWA00002349	10/13/25	icf IRB #1	08/14/21	1202044124

# 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
Alisha Etheredge	12/26/2021	09/25/2023			Co- Investigator	epq5@cdc.gov	770- 488- 7884	PROGRAM SERVICES TEAM

Amy Lavery	08/01/2022	08/05/20	022	Co- Investigator	nqz6@cdc.gov	404- 498- 5304	HEALTH STUDIES
Brian Kennedy	06/06/2022			Co- Investigator	xko3@cdc.gov	770- 488- 0048	DIVISION OF ENVIRONMENTAL HEALTH SCIENCE AND PRACTICE
Stephanie Foster	07/11/2022			Principal Investigator	sob4@cdc.gov	770- 488- 3870	DATA AND ANALYSIS SECTION
Suzanne Condon	12/24/2023			Co- Investigator	Irl8@cdc.gov	404- 403- 0446	NATIONAL CENTER FOR ENVIRONMENTAL HEALTH

## Data

## **DMP**

Proposed Data Collection Start Date: 9/1/21
Proposed Data Collection End Date: 12/31/22
Proposed Public Access Level: Public

Public Access Justification: Focus group discussion data will be collected as a result of activities designed and funded by CDC and therefore data generated from these activities will be made public. While transcripts will be generated, results summarizing

the themes will be developed devoid of personal identifying information in summary format that will be provided to

the CDC by the contractor. These summary results will be made available.  $\label{eq:cdc} % \begin{center} \beg$ 

How Access Will Be Provided for Data: While transcripts will be generated, results summarizing the themes will be developed devoid of personal

identifying information in summary format will be provided to the CDC by the contractor. These summary results

will be made available.

Plans for Archival and Long Term

Preservation:

Transcripts and notes collected from the focus group discussions will be destroyed by ICF once the summary report

has been submitted to CDC.

# **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										

