



Project Determination

Environmental Health Specialists Network (EHS-Net) Program OMB Generic Package

Project ID: 0900f3eb81c8e66b
Accession #: NCEH-WFEHSB-2/2/21-8e66b
Project Contact: Erin Moritz
Organization: NCEH/ATSDR/DEHSP/WFEHSB/FT
Status: Project In Progress : PRA Revision
Intended Use: Project Determination
Estimated Start Date: 02/01/25
Estimated Completion Date: 01/31/28
CDC/ATSDR HRPO/IRB Protocol#:
OMB Control#: 0920-0792
End of Human Research Date:

Description

Priority

Standard

Date Needed

08/05/24

CDC Priority Area for this Project

Other CDC Priority - Decreasing health risks from environmental exposures

Determination Start Date

06/25/21

Description

This is the OMB package for the EHS-Net food safety research program generic clearance. Generic clearance is the OMB terminology for a 'blanket' clearance for several studies. Our 8 EHS-Net funded sites conduct 2 or 3 multisite data collections in restaurants per funding cycle. This generic clearance allows for

a shortened clearance process (i.e., 6 months) for these data collections. If we did not obtain generic clearance for these EHS-Net studies, clearance for each individual study would take at least 12 months, compared to the 6 months it would take with a generic clearance. The current generic clearance expires 1/31/2025.

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 goal of this food safety research program (called EHS-Net) is to collect data in retail food establishments that will identify and address environmental factors (e.g., manager food safety certification, equipment condition, etc.) associated with retail-related foodborne illness and outbreaks.

Objective

The information collected from establishments will be used by CDC to develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry.

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 Population to be Included/Represented

Businesses

Tags/Keywords

food safety

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

Individual Interview (Quantitative); Observation

Methods

interviews/assessments with restaurant staff; observations of restaurant kitchen environments and food workers preparing food

Collection of Info, Data, or Bio specimens

interviews/assessments with restaurant staff; observations of restaurant kitchen environments and food workers preparing food

Expected Use of Findings/Results and their impact

The information collected from establishments will be used by CDC to develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry.

Could individuals potentially be identified based on information collected?

No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award	Budget Amount
CDC Cooperative Agreement	Environmental Health Specialists Network - \$1,540,000 annually	EH-20-001	2020	5	

HSC Review

HSC Attributes

Non-Human/Non-Animal Material

Yes

Regulation and Policy

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

Yes

Estimated number of study participants

376 restaurants per study

Population - Children

N/A

Page:

Population - Minors

N/A

Page:

Population - Prisoners

N/A

Page:

Population - Pregnant Women

N/A

Page:

Population - Emancipated Minors

N/A

Page:

Suggested level of risk to subjects

Minimal

Do you anticipate this project will be exempt research or non-exempt research

Exempt

Category 1: Education Practices

No Selection

Category 2: Educational tests, surveys, interviews, or observation of public behavior

No Selection

Category 3: Benign Behavioral Interventions and Collection of Information

No Selection

Category 4: Secondary Research for Which Consent is not Required

Regulation and Policy

No Selection

Category 5: Research and Demonstration Projects

No Selection

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

No Selection

Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required

No Selection

Category 8: Secondary Research for Which Broad Consent is Required

No Selection

Will you be working with an outside Organization or Institution? Yes

Institutions

Institution	FWA #	FWA Exp. Date	Funding	Funding Restriction Amount
Harris County, Texas Department of Health			EH-20-001	
Franklin County, OH Department of Health			EH-20-001	
Fund for Public Health NY	FWA00023694	08/22/28	EH-20-001	
Minnesota Department of Health	FWA00000072	07/05/29	EH-20-001	
New York State Dept of Hlth	FWA00003700	08/26/29	EH-20-001	
Rhode Island Department of Health	FWA00006141	09/13/27	EH-20-001	
Southern Nevada Health District	FWA00023704	10/23/24	EH-20-001	
Tennessee Department of Health	FWA00000379	01/18/27	EH-20-001	

Institution	Funding Restriction Percentage	Funding Restriction Reason	Funding Restriction has been lifted
Harris County, Texas Department of Health			
Franklin County, OH Department of Health			
Fund for Public Health NY			
Minnesota Department of Health			
New York State Dept of Hlth			
Rhode Island Department of Health			
Southern Nevada Health District			
Tennessee Department of Health			

Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution
Harris County, Texas Department of Health				
Franklin County, OH Department of Health				
Fund for Public Health NY				
Minnesota Department of Health				
New York State Dept of Hlth				
Rhode Island Department of Health				
Southern Nevada Health District				
Tennessee Department of Health				

Institution	Regulatory Coverage	IRB Review Status
Harris County, Texas Department of Health		
Franklin County, OH Department of Health		
Fund for Public Health NY		
Minnesota Department of Health		
New York State Dept of Hlth		
Rhode Island Department of Health		
Southern Nevada Health District		
Tennessee Department of Health		

Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status
Harris County, Texas Department of Health			
Franklin County, OH Department of Health			
Fund for Public Health NY	New York City Dept of Hlth & Mental Hygiene IRB #1	08/06/23	
Minnesota Department of Health			
New York State Dept of Hlth			
Rhode Island Department of Health	RHODE ISLAND STE DEPT HLTH IRB #1	04/03/22	
Southern Nevada Health District	U of Nevada, Las Vegas IRB #1 -- Biomedical Sciences	01/03/23	
Tennessee Department of Health			

Institution	IRB Approval Date	IRB Approval Exp. Date	Relying Institution IRB
Harris County, Texas Department of Health			
Franklin County, OH Department of Health			
Fund for Public Health NY			
Minnesota Department of Health			
New York State Dept of Hlth			
Rhode Island Department of Health			
Southern Nevada Health District			
Tennessee Department of Health			

Staff									
Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Citi Good Laboratory Practice Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
LauraBrown	08/07/2026		07/18/2025			Program Lead	lrg0@cdc.gov	770-488-2	WATER FOOD AND ENVIRONMENTAL HEALTH SERVICES BRANCH

DMP	
Proposed Data Collection Start Date	02/01/25
Proposed Data Collection End Date	08/31/27
Proposed Public Access Level	Public
Public Access justification	These data will be anonymous so can be shared.
How Access Will Be Provided for Data	We will release data files from the studies with our publications through CDC Stacks.
Plans for archival and long-term preservation of the data	We will archive for 10 years in CDC Stacks.

Spatiality (Geographic Location)

Country	State/Province	County/Region
United States		

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Research Not Involving Human Subjects <i>45 CFR 46.102(e)</i>	07/29/24	Ding_Yan (Shirley) (yad6) CIO HSC
PRA: PRA Applies		07/29/24	Ding_Yan (Shirley) (yad6) CIO OMB / PRA
ICRO: PRA Applies	OMB Approval date: 01/26/22 OMB Expiration date: 01/31/25	08/05/24	Zirger_Jeffrey (wtj5) ICRO Reviewer