



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

Print Date: 7/20/21

Title: Environmental Health Specialists Network (EHS-Net) Program OMB Generic Package
Project Id: 0900f3eb81c8e66b
Accession #: NCEH-WFEHSB-2/2/21-8e66b
Project Contact: Laura G Brown
Organization: NCEH/ATSDR/DEHSP/WFEHSB
Status: Pending Clearance : PRA Revision
Intended Use: Project Determination
Estimated Start Date: 09/01/2021
Estimated Completion Date: 08/31/2024
CDC/ATSDR HRPO/IRB Protocol #:
OMB Control #: 0920-0792

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>	7/20/21	Davis_Stephanie I. (sgd8) CIO HSC
PRA: PRA Applies		3/19/21	Abel_Jason A. (jza5) CIO OMB / PRA
ICRO: Returned with No Decision		3/19/21	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard
Date Needed: 04/01/2021
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 8/31/2021.

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 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 this project include interventions, services, or policy change work aimed at improving the health of groups who have Not Selected

been excluded or marginalized and/or decreasing disparities?:

Project does not incorporate elements of health equity science: Not Selected

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

Expected Use of Findings/Results: 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 Budget Yr	# Years 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 be submitted to the IRB office Yes

Estimated number of study participants 376 restaurants per study

Population - Children N/A

Population - Minors N/A

Population - Prisoners N/A

Population - Pregnant Women N/A

Population - Emancipated Minors N/A

Suggested level of risk to subjects Minimal Do you anticipate this project will be exempt research or non-exempt research Exempt

Category 1: Educational 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 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

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Harris County, Texas Department of Health					EH-20-001
Franklin County, OH Department of Health					EH-20-001
Fund for Public Health NY	FWA00023694	12/09/20	New York City Dept of Hlth & Mental Hygiene IRB #1	08/06/23	EH-20-001
Minnesota Department of Health	FWA00000072	03/24/22			EH-20-001
New York State Dept of Hlth	FWA00003700	03/11/26			EH-20-001
Rhode Island Department of Health	FWA00006141	09/09/25	RHODE ISLAND STE DEPT HLTH IRB #1	04/03/22	EH-20-001
Southern Nevada Health District	FWA00023704	10/23/24	U of Nevada, Las Vegas IRB #1 -- Biomedical Sciences	01/03/23	EH-20-001
Tennessee Department of Health	FWA00000379	02/07/22			EH-20-001

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
Laura Brown	12/20/2021		12/20/2021		Program Lead	lrg0@cdc.gov	770-488-2	WATER FOOD AND ENVIRONMENTAL HEALTH SERVICES BRANCH

Data

DMP

Proposed Data Collection Start Date: 1/1/22

Proposed Data Collection End Date: 8/31/24

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: We will archive for 10 years in CDC Stacks.

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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