



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

Print Date: 12/11/20

**Title:** Restaurant Employee Health Policy Study  
**Project Id:** 0900f3eb81a574d9  
**Accession #:** NCEH-FT-11/1/19-574d9  
**Project Contact:** Kramer\_Adam (ank5)  
**Organization:** NCEH/ATSDR/DEHSP/WFEHSB/FT  
**Status:** **Pending Clearance : PRA Revision**  
**Intended Use:** **Project Determination**  
**Estimated Start Date:** 12/02/2019  
**Estimated Completion Date:** 09/29/2020  
**CDC/ATSDR HRPO/IRB Protocol #:**  
**OMB Control #:** 0920-1227

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: <b>Does NOT Require HRPO Review</b>	Research Not Involving Human Subjects <i>45 CFR 46.102(e)</i>	12/11/20	Davis_Stephanie I. (sgd8) CIO HSC
PRA: <b>PRA Applies</b>		12/11/20	Davis_Stephanie I. (sgd8) CIO OMB / PRA
HRPO: <b>HRPO/IRB Approves</b>	HRPO/IRB decision date: 10/7/20 IRB Expiration date: 12/31/30	10/17/20	Vann_Jerrell A. (jiv4) HRPO Reviewer
ICRO: <b>Returned with No Decision</b>		9/30/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

## Description & Funding

### Description

**Priority:** Standard  
**Date Needed:** 12/02/2019  
**Determination Start Date:** 11/18/20

### Description:

This study will be conducted by the Environmental Health Specialists Network (EHS-Net) program, a collaborative project of the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and eight local and state public health departments (Franklin County [Ohio], New York, New York City [New York], Minnesota, Rhode Island, Tennessee, Southern Nevada Health District [Nevada], and Harris County [Texas]). This is an EHS-Net intervention study designed to assess whether an educational intervention will result in restaurants either developing or modifying their sick worker management plans. The study will occur in randomly selected restaurants in the EHS-Net sites. The study will use a quasi-experimental pre- and post-test design. The study will include two randomly assigned groups (intervention and control). Each of the eight EHS-Net sites will collect data in twenty restaurants in each group for a total of 320 restaurants. In both the intervention and the control groups, data collectors will conduct an initial site visit in which they will interview the manager and observe food safety practices within the restaurant. Then, on this same visit, the restaurants in the intervention group will receive an educational intervention comprised of an explanation of the need to develop sick worker management plans and a toolkit (with sample policies). The restaurants in the control group will not receive this intervention at this time. Three to six months later, the intervention and control restaurants will be visited again, and a similar data collection will occur. At this second visit, the intervention will be provided to control restaurants. If the intervention is successful, based on either the development or modification of restaurant sick worker policies, a telephonic follow up interview will occur with previous control restaurants to see if their policies have changed.

**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

<b>CIO Emergency Response Name:</b>	Not selected
<b>Epi-Aid Name:</b>	Not selected
<b>Assessment of Chemical Exposure Name:</b>	Not selected
<b>Goals/Purpose</b>	Examine whether an educational intervention will result in restaurants either creating or modifying their sick worker management plans. Sick food workers are the leading source of norovirus outbreaks attributed to restaurants. These plans can help restaurants prevent sick workers from working and consequently reduce outbreaks.
<b>Objective:</b>	The objective of the study is to determine if an educational intervention leads restaurants to create or improve their sick worker management plans.
<b>Activities or Tasks:</b>	New Collection of Information, Data, or Biospecimens
<b>Target Populations to be Included/Represented:</b>	Other
<b>Tags/Keywords:</b>	Food Services, Sick food worker
<b>CDC's Role:</b>	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
<b>Method Categories:</b>	Individual Interviews (Qualitative); Observation
<b>Methods:</b>	Data collectors (EHS-Net site staff which are experienced food safety professionals) will interview restaurant managers about: restaurant policies around sick food workers and preventing illness transmission; their demographics; and their beliefs about sick food workers. Data collectors will also collect observation data in the restaurant kitchen on implementation of practices designed to prevent illness transmission from a sick food worker.
<b>Collection of Info, Data or Biospecimen:</b>	Information will be obtained through interview and observation.
<b>Expected Use of Findings/Results:</b>	The findings will be used to inform public health practice in developing interventions to keep sick food workers from working.
<b>Could Individuals potentially be identified based on Information Collected?</b>	No

## Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Cooperative Agreement	Environmental Health Specialists Network	EH20-001	2020	5

## HSC Review

### Suggested level of IRB review

<b>Expedited review is suggested</b>	Yes
<b>1a - Study of drugs not requiring Investigational New Drug exemption from FDA</b>	No Selection
<b>1b - Study of medical devices not requiring Investigational Device Exemption from FDA</b>	No Selection
<b>2a - Collection of blood from healthy, non-pregnant adults; below volume and frequency limits, minimally invasive</b>	No Selection
<b>2b - Collection of blood from other adults and children; below volume and frequency limits, minimally invasive</b>	No Selection
<b>3 - Prospective noninvasive collection of biological specimens for research purposes</b>	No Selection
<b>4 - Collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, x-rays, or microwaves</b>	No Selection
<b>5 - Research that uses previously collected materials</b>	No Selection
<b>6 - Collection of data from voice, video, digital, or image recordings made for research purposes</b>	No Selection
<b>7 - Research that uses interview, program evaluation, human factors, or quality assurance methods</b>	Yes

### HSC Attributes

<b>Non-Human/Non-Animal Material</b>	Yes
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**Other - This is a research study about restaurant food safety policies and practices and not human subjects.** Yes

### Additional Ethical Considerations

This is a re-determination of research study previously reviewed and approved as CDC Protocol 7261 (Restaurant Employee Health Policy Study). The PI is Dr. Adam Kramer (ank5). After careful deliberation of the research aims, it has been determined that this protocol is "research not involving identifiable human subjects" and will not require IRB review. This is a research study about restaurant food safety policies and practices and not about human subjects.

### Regulation and Policy

**Do you anticipate this project will be submitted to the IRB office** No

**Estimated number of study participants**

**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 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 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

No Selection

Exception is requested to PHS informing those bested about HIV serostatus

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

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Franklin County Public Health					EH20-001
Centers for Disease Control & Prevention	FWA00001413	10/31/24			
Harris County Public Hlth & Environmental Services	FWA00009349	12/11/19			EH20-001
Minnesota Department of Health	FWA00000072	03/24/22			EH20-001
New York City Dept of Hlth & Mental Hygiene	FWA00009459	08/06/25			EH20-001
New York State Dept of Hlth	FWA00003700	10/01/25			EH20-001
Rhode Island Department of Health	FWA00006141	09/09/25	RHODE ISLAND STE DEPT HLTH IRB #1	04/03/22	EH20-001
Southern Nevada Health District	FWA00023704	10/23/24			EH20-001
Tennessee Department of Health	FWA00000379	02/07/22			EH20-001

### 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
Adam Kramer	05/31/2022		12/31/2022		Principal Investigator	ank5@cdc.gov	404-498-1228	FOOD
Laura Brown	12/20/2021		12/20/2021		Co-Investigator	lrg0@cdc.gov	770-488-2	WATER FOOD AND ENVIRONMENTAL HEALTH SERVICES BRANCH

## Data

### DMP

**Proposed Data Collection Start Date:** 12/2/19

**Proposed Data Collection End Date:** 9/29/20

**Proposed Public Access Level:** Public

**Public Access Justification:**

The dataset may have identifying information if combined with other data that could lead to the identification of the restaurant and potentially to the person responding to the survey. Specific fields would not be allowed to be released to protect the privacy of the respondents.

**How Access Will Be Provided for Data:**

Data will be released in aggregate format. Any non-aggregated data will have EHS-Net site identifiers and any other potential identifiers omitted from release.

**Plans for Archival and Long Term Preservation:**

### Spatiality

Spatiality (Geographic Locations) yet to be added .....

### Dataset

Dataset Title	Dataset Description	Data Publisher/Owner	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
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		Public Access Level						
Dataset yet to be added...								



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