

Assessment of Ill Worker Policies Study

OMB No. 0920-NEW

New Information Collection Request

Supporting Statement - A

Submitted: May 2018

Program Official:
Adam Kramer Sc.D., M.P.H., R.S.
Environmental Health Officer
Centers for Disease Control and Prevention
National Center for Environmental Health
Emergency and Environmental Health Services
Environmental Health Services Branch
4770 Buford Highway, NE F – 58
Atlanta, GA 30341-3724
404-498-1228 (Phone)
770-488-3635 (Fax)
E-mail: ank5@cdc.gov

Supporting Statement Part A

Table of Contents

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Assurance of Confidentiality Provided to Respondents
11. Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

List of Attachments

- Attachment 1 – Authorizing Legislation
- Attachment 2 – 60-day Federal Register Notice
- Attachment 3a – Industry Partners
- Attachment 3b – Publications
- Attachment 4 – Telephone Manager Recruiting Script
- Attachment 5 – Manager Informed Consent and Interview Form
- Attachment 6 – Manager Interview Marking Guide
- Attachment 7 – Food Worker Informed Consent and Survey
- Attachment 8 – Restaurant Environment Observation Form
- Attachment 9 – Guide To Developing A Restaurant Ill Worker Management Plan
- Attachment 10 – NCEH-ATSDR Research Determination Form
- Attachment 11 – Protocol

Supporting Statement Part A

Goal of the study: This study has two goals 1) to assess restaurant ill worker management practices and plans; and 2) examine the effectiveness of an educational intervention for restaurants to develop enhanced ill worker management practices.

Intended use of the resulting data: Data from this study can be used to develop educational materials, trainings, and tools that are targeted towards improving retail food establishment ill worker management practices. If the intervention is successful, it will be provided to state and local food safety regulatory agencies as a model practice for working with restaurants to develop ill worker management plans and enhance their practices of keeping ill workers from working with food.

Methods to be used to collect data: The study proposes using a quasi-experimental non-equivalent group pre- post-test design. It will involve interviews with a restaurant manager, survey of food workers, and an observation of the restaurant practices. The study will have an intervention and a control group that will be assessed pre- and post-intervention. If the intervention is successful, it will be provided to the control restaurants and an additional follow up assessment will occur for these facilities.

The subpopulation to be studied: The population to be studied will be voluntarily participating restaurants in the Environmental Health Specialists Network (Minnesota; New York City; New York; Tennessee; Rhode Island; California; Southern Nevada Health District; and Harris County, Texas).

How data will be analyzed: Initial analysis of the success of the intervention will be performed with a chi-square analysis.

Supporting Statement Part A

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), is requesting Paperwork Reduction Act (PRA) clearance for a new three-year information collection entitled “Assessment of Ill Worker Policies Study.” This information collection request (ICR) will be conducted in partnership with the Environmental Health Specialists Network (EHS-Net), CDC cooperative agreement EH15-001. Data will be collected by personnel in eight state and local health departments participating in EHS-Net. This data collection focuses on pre-and post-survey of staff knowledge, attitudes, and practices concerning ill food workers in retail food establishments and includes an educational intervention to encourage restaurant managers to develop ill food worker management plans. A standard ICR is being proposed for PRA clearance as the activities (outlined above) are outside the scope of the current EHS-Net generic (OMB No. 0920-0792; expiration 9/30/2018). The PRA clearance for this ICR needs to be in place by 02/08/2018, to effectively complete data collection per schedule.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1). The 60-day Federal Register Notice (FRN) was published on July 14, 2017 (Attachment 2).

CDC developed the EHS-Net program to conduct studies designed to identify and understand environmental factors associated with foodborne illness outbreaks and other food safety issues (e.g. ill workers). These data are essential to environmental public health regulators’ efforts to respond more effectively to and prevent future foodborne illness outbreaks and food safety-associated events.

CDC’s EHS-Net is a collaborative project of the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and eight state and local public health departments (California, Minnesota, New York, New York City, Rhode Island, Tennessee, Southern Nevada Health District, and Harris County Texas). CDC’s funding to these state and local health departments, enables them to collaborate with CDC on study design, collecting study data, and co-analyzing study data. The federal partners provide funding and input into study design and data analysis. The EHS-Net workgroup has representatives from both FDA and USDA, while FDA mandates that ill food workers do not work with food, this study goes further to examine the specific policies and to encourage development of a plan that addresses the reasons that employees have reported for working while sick. Industry partners that support this initiative, its goals and research by collaborating on study design and data analysis are in Attachment 3a. A summary of the research conducted through this partnership has resulted in 30 publications (Attachment 3b).

Supporting Statement Part A

Ill food workers are an important cause of foodborne illness outbreaks; they are responsible for a quarter of all restaurant-related outbreaks (Angelo, 2016). And 20% of food workers work while ill with foodborne illness symptoms annually (Sumner, 2011). Reducing the rate at which ill workers work would lower the burden of foodborne illness outbreaks in the United States. The FDA Food Code, a model food code that serves as the basis for all state and local regulatory food codes in the U.S., includes provisions for restaurants aimed at preventing ill workers from working while ill with foodborne illness. These provisions include excluding an employee that is symptomatic with vomiting and/or diarrhea or diagnosed with certain illnesses (e.g., Norovirus, *Salmonella typhi*, etc.). The Food Code also includes provisions aimed at minimizing the spread of illness by ill workers, such as by limiting bare hand contact with ready-to-eat food items.

Recent research shows that the existence of ill worker policies is linked with lower rates of workers working while ill (Sumner et al., 2011) and lower foodborne illness outbreak rates (Kambhampati et al., 2016), indicating that they are an important component of a restaurant's food safety plan. Yet, 40% of states have not adopted this provision of the Food Code (Kambhampati et al., 2016). And even in states that have adopted this provision, not all restaurants implement them (Norton, 2015).

Given these data showing the importance of these policies to food safety and the lack of them, the jurisdictions funded through our EHS-Net cooperative agreement wished to develop and assess the effectiveness of an educational intervention designed to motivate restaurant managers to develop, implement, and enforce comprehensive ill worker management plans, plans that would include relevant Food Code provisions. The intervention focuses on ensuring that the ill worker management plans address barriers to workers staying home when ill, as identified in previous research (Sumner et al., 2011). Finally, the intervention focuses on improving restaurant policies and practices (e.g., wearing gloves while handling food) that would minimize the spread of illness by ill workers.

This data collection supports the U.S. Department of Health and Human Services' Healthy People 2020 goal to "Improve food safety and reduce foodborne illnesses." Specifically, these data can be used to prepare educational materials, trainings, and tools that are targeted towards improving retail food establishment ill worker management practices.

2. Purpose and Use of the Information Collection

The purpose of this ICR is to evaluate the effectiveness of an educational intervention for restaurants. This study will answer the following questions about the intervention:

1. Does the intervention lead to the development or enhancement of comprehensive ill worker management plans, that include Food Code provisions and that address barriers to workers staying home while ill?
2. Does the intervention improve restaurant policies and practices to minimize the spread of illness by ill workers?
3. Does the intervention improve food employee knowledge and attitudes towards working while ill?

Supporting Statement Part A

The following table describes the measures that will be used to answer these questions.

Evaluation question	Measures
1. Does the intervention lead to the development or enhancement of comprehensive ill worker management plans, plans that include Food Code provisions?	Increase after intervention delivery in: <ul style="list-style-type: none"> • Frequency of restaurants with ill worker management plans • Frequency of restaurants with specific Food Code provisions (e.g., exclusion or restriction of ill employees) in their ill worker management plans • Frequency of restaurants with provisions that address barriers (e.g., maintaining a list of available employees) in their ill worker management plans
2. Does the intervention improve restaurant policies and practices to minimize the spread of illness by ill workers?	Increase after intervention delivery in the frequency of restaurants with policies and practices that minimize the spread of illness by ill workers including: <ul style="list-style-type: none"> • Use of gloves when preparing food • Existence of policy on how to clean and sanitize after a vomiting incident in the restaurant • Increased hand hygiene practices
3. Does the intervention improve food employee knowledge and attitudes towards working while ill?	Improvement after intervention delivery in the knowledge and attitudes of food employees towards working with food while ill.

Because restaurant policies and practices are influenced by a number of restaurant characteristics, such as number of meals served daily, ownership (independent vs. chain), and manager and worker food safety characteristics, knowledge, attitudes, and practices, we are also collecting data on these variables. They will be included in our analyses, where appropriate.

Intervention

The intervention will be delivered in restaurants by EHS-Net site staff, who are food safety experts. The intervention contains three components. First, EHS-Net staff will talk with the kitchen manager and will cover the following topics:

- 1) the number of illnesses and outbreaks caused by ill restaurant workers,
- 2) the importance of preventing ill workers from working,
- 3) the importance of ill worker management plans to help reduce ill worker rates,
- 4) provisions included in comprehensive ill worker management plans,
- 5) known barriers to workers staying home while ill and potential solutions to those barriers
- 6) provisions concerning minimizing the spread of illness.

Second, to emphasize the importance of preventing customers from getting sick from ill workers, EHS-Net staff will show the manager a video testimonial of how foodborne illness has affected victims and their families (videos are publically available on the FDA website).

Supporting Statement Part A

Third, EHS-Net staff will provide the manager with a guide that contains comprehensive information and policy templates that can be used to develop their own ill worker management plans.

Implementation

Intervention restaurants. Twenty restaurants in each EHS-Net site will be randomly selected to receive the intervention. After the restaurants have agreed to participate in the study, EHS-Net site staff will visit these restaurants, collect pre-intervention data (Attachments 5,7, and 8) and then deliver the intervention to the restaurant managers. Approximately 6 months later, EHS-Net site staff will visit the restaurants again, and collect post-intervention data on the measures of interest. The timeframe for the follow up is based on individual site logistical constraints, and the EHS-Net site staff indicated that this timeframe would be needed.

Control restaurants. During the same timeframe, twenty restaurants in each EHS-Net site will be randomly selected to serve as controls for the intervention restaurants. This control group will allow us to control for events that happen during the study period (other than our intervention) that may affect restaurant policies and practices (e.g., a large foodborne outbreak with elevated media coverage). After the restaurants have agreed to participate in the study, EHS-Net site staff will visit these restaurants, collect the same pre-intervention data collected in the intervention restaurants, but they will not deliver the intervention. Approximately 6 months later, EHS-Net site staff will visit the restaurants again, and collect post-intervention data on the measures of interest. If the intervention shows preliminary success, it will be provided to the control restaurants at the follow-up and a third site visit will occur in these restaurants. Initial success for the intervention will be measured by if three or more intervention restaurants either develop a written ill worker management plan (if they did not have one at the pre-intervention evaluation) or enhanced their policies (e.g., added provisions addressing reasons why ill workers reported working while ill).

Data collection. Both pre- and post-intervention restaurant visits, for both intervention and control restaurants, will be comprised of the following:

- Manager interview- will collect data on restaurant characteristics and existing ill worker management plans, and manager characteristics, and ill worker knowledge, attitudes, and practices
- Food worker survey- will collect data on food worker characteristics, and ill worker knowledge, attitudes, and characteristics
- Structured observation- will collect data on restaurant characteristics and practices to minimize the spread of illness by ill workers.

Analysis of these data will determine if the measures of interest increased as expected. For example, we will determine if the frequency of restaurants with ill worker management plans increased pre- to post- intervention.

Supporting Statement Part A

Data collection will include voluntarily participating restaurants in selected geographical areas as stated in section A.1. While the number of areas included is small, they are demographically diverse and provide good geographical coverage of the U.S. (northeast, mid-west, south, and west). When the statistical methods outlined here for ensuring a representative sample in the current study are used, the results of the collection can be used to generalize to the population of retail food establishments that are a part of the network.

The data collected by this study can be used to identify if an educational intervention can be used to change restaurant processes. If it is effective, it can be shared with state and local food safety regulatory programs. The study will also inform how well (or not) prepared restaurants are to manage ill food workers, by the existence of initial practices, and if an educational intervention can help prepare them to handle ill workers and prevent the spread of illness. The goal of this information collection is to assist CDC and other federal, state, and local food safety programs to develop food safety prevention, intervention recommendations, and tools for food safety programs and the restaurant industry. For example, if the intervention is successful, CDC can disseminate the information and encourage food safety programs and the restaurant industry to implement these programs. CDC can also disseminate information on the knowledge, attitudes, and practices of the restaurant workers and encourage food safety programs and the restaurant industry to address these gaps. Ultimately, these types of actions can contribute to a decrease in the number of incidents of foodborne illness caused by an ill food worker.

3. Use of Improved Information Technology and Burden Reduction

The primary burden to respondents of participation in this study involves their participation in interviews and surveys (Attachments 5 and 7). It is less burdensome for respondents to provide interview responses verbally than to have to type their responses into an electronic reporting system. Thus, we have chosen not to collect interview data electronically, but rather, collect the data through face-to-face verbal interviews with respondents. Study personnel will record responses on paper-and-pencil forms (Attachment 5). Structured food worker surveys will be provided on either a paper and pencil form (Attachment 7) or if resources are available on a tablet computer (which would mirror the paper form). The information for the surveys is standardized and it is expected that either method will take a similar amount of time.

Participation in this data collection is voluntary, and every effort was made to keep the data collection as short as possible and still meet the needs of the data collection.

4. Efforts to Identify Duplication and Use of Similar Information

This data collection will not be a duplication of effort. We have searched relevant scientific bibliographical databases (e.g., PubMed, Ovid, Agricola), attended national meetings (e.g. National Environmental Health Association, International Association of Food Protection), and consulted with other organizations (e.g., FDA, USDA-FSIS) concerning research on this topic.

Supporting Statement Part A

Few studies exist on this topic; the research that exists has been conducted in small geographical regions or with convenience samples. Consequently, data are needed from a random sample of a geographically and demographically diverse population of restaurants. This study will do this.

5. Impact on Small Businesses or Other Small Entities

We expect that about half of the restaurants contacted for participation in this study will be small businesses. Given that small businesses are likely to have different experiences and practices than larger businesses, it is important that small businesses be included in this data collection. Short forms for small businesses will not be developed. We plan to ask the same questions to both large and small restaurants. Small businesses may not have similar written plans as larger businesses, however both size restaurants have a similar issue of employees potentially working while ill, and increasing the risk to the public of foodborne illness. The surveys developed will strive to hold the number of questions to the minimum needed for the intended use of the data.

6. Consequences of Collecting the Information Less Frequently

All participating restaurants will be interviewed in the study duration a minimum of two times pre- and post-intervention (Attachments 5 and 7), if the intervention is proving successful, it will be provided to the control restaurants on the second site visit and a third site visit will be conducted in these establishments to further gauge the effect of the intervention. If this data collection is not conducted, it will be more difficult for CDC, other federal, state, and local food safety programs, and the food service industry to address the development of ill worker management plans along with gaps in restaurant ill worker knowledge, attitudes, and practices. In turn, it will be more difficult to decrease the number of incidents of foodborne illness caused by ill food workers and for CDC to fully address the U.S. Department of Health and Human Services' Healthy People 2020 Goal to "Improve food safety and reduce foodborne illnesses." There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this data collection. This request fully complies with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-day Federal Register Notice was published on July 14, 2017 in Vol. 82 No. 134 pp. 32551-3 (Attachment 2) and no comments were received.

Personnel from the EHS-Net sites worked with CDC to develop this data collection in 2017. Additionally, FDA and USDA, EHS-Net partners, were also consulted on the data collection.

Supporting Statement Part A

CDC EHS-Net Sites	
Brenda Faw Senior Environmental Health Specialist CA Dept. of Health brenda.faw@cdph.ca.gov 916-445-9548	David Nicholas Research Scientist NY Dept. of Health dcn01@health.state.ny.us 518-402-7600
Daniel O’Halloran Research Assistant NYC Dept. of Health dohalloran@health.nyc.gov 646-632-6523	Nicole Hedeem Epidemiologist MN. Dept. of Health Nicole.hedeem@state.mn.us 651-201-4075
Brendalee Viveiros RI EHS-Net Coordinator RI Dept. of Health Brendalee.Viveiros@health.ri.gov 401-222-4774	Lauren DiPrete Senior Coordinator Southern Nevada Health District DiPrete@snhdmail.org 702-759-1504
Deanna Copeland Environmental Health Specialist Harris County Health Department dcopeland@hcpbes.org 713-274-6443	Danny Ripley Food Inspector II TN Dept. of Health Danny.ripley@nashville.gov 615-340-5620
Federal Partners	
Laurie Williams Consumer Safety Office Office of Food Safety FDA/CFSAN Laurie.Williams@fda.hhs.gov 240-402-2938	Stephanie Mickelson Epidemiologist USDA stephanie.mickelson@fns.usda.gov 703-305-2894

9. Explanation of Any Payment or Gift to Respondents

There will be no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The proposed project has been reviewed by the NCEH Information Systems Security Officer (ISSO) who has determined that the Privacy Act does not apply to this collection. Therefore a system of records notice (SORN) will not be created. No assurances of confidentiality will be provided to respondents. While face-to-face interviews will be conducted, CDC will not be directly engaged in data collection, will not interact with any respondents, nor will we receive identifying information on any of the participating restaurants or staff from the EHS-Net sites. The NCEH Human Subjects Contact has reviewed this project and has classified this project as research, but CDC is not engaged in research. Therefore, this project does not require review beyond the center human subjects contact (Attachment 10). The CDC’s Institutional Review Board (IRB) approval is also not required for the project. However, sites will obtain approval from their respective IRBs as appropriate.

Supporting Statement Part A

Information in identifying form (IIF) will not be transmitted to CDC. IIF will only be collected for the restaurant to allow for the follow up visit. After that visit the IIF will be destroyed. The individual sites will assign a code number to the restaurant and only that code number will be reported to Environmental Health Specialists Network Information System (EHSNIS). Subsequent to the follow up visits, the restaurant name and address will no longer be needed and will be destroyed by the sites.

No paper files will be delivered to CDC. Instead, data collectors will enter all paper-and-pencil responses into the EHSNIS. Data will be reported to CDC through a web-based information system, the EHSNIS. All electronic data will be stored on secure CDC networks. Access to the data will be limited to those with a bona fide need-to-know in order to perform job duties related to the project. User accounts will be issued to the specialists who will serve as the administrator of the system for his or her own site. Through these password protected accounts, users will be granted privileges including entering and accessing data, and correction and deletion of records capabilities. As previously stated, all data records are owned by the site entering the data. Each site possesses ownership of its records and must grant permission to other sites or agencies who would like to use the data.

Verbal consent will be obtained from respondents. As a part of the informed consent, respondents will be made aware of their ability to retrieve a summary of the study's findings by contacting their health department 12 months following data collection. The manager's informed consent script can be found at the beginning of the manager interview (Attachment 5); the food workers informed consent script are combined with the recruiting script and can be found at the beginning of the survey form (Attachment 7).

Participation in this data collection is voluntary, and respondents are informed of the voluntary nature of the data collection during recruiting and in the informed consent script.

All data records are owned by the site entering the data. Each site has authority over its records and must grant permission to other sites or agencies who would like to use the data. Each site's data will be stored for twelve years.

11. Justification for Sensitive Questions

There are no sensitive questions in this data collection.

12. Estimates of Annualized Burden Hours and Costs

The goal for the 3-year program period is to include 320 restaurants (half to be assigned to the intervention and half to be assigned to the control restaurant groups). The table below shows how the annual number of respondents is derived.

Supporting Statement Part A

Manager recruiting script	712/3 yrs. = 237 per year
Total number of participating restaurants	40 restaurants per site* 8 sites = 320 for 3 yrs.
Total number of intervention or control restaurants	320/3 yrs./2 respondent groups = 54 per year
Manager interviews (at each assessment) for intervention or control restaurants	(same as above) 54 per year
Food worker interviews (at each assessment) for intervention or control restaurants	54 restaurants per year * 5 workers per restaurant = 270 workers per year
Health departments observations (at each assessment) for intervention or control restaurants	54 per year
NOTE: Control restaurants may have an additional site visit depending upon the success of the intervention which include activities same as above	

Estimated annualized burden hours, averaged over the three-year period, are presented for each study respondent group and in total. Eight sites will collect data for this study; each site will collect data in 40 restaurants (20 that receive the intervention initially and 20 that serve as controls). If the intervention is successful, the control restaurants will also receive the intervention and an additional assessment visit to further determine if the intervention was effective. Thus, there will be a total 320 restaurant manager respondents (40 restaurants * 8 sites) for three years. We expect a manager response rate of 45%; thus we will need to contact 712 restaurant managers (237 per year) via telephone in order to meet our goal of 320 respondents (total 107 per year or 54 for each group). Each respondent to the script will respond only once, and the average burden per response will be approximately 3 minutes (12 annualized hours).

In the intervention restaurants, all participating restaurants in this group will have two visits. In the first visit, the study staff will collect baseline data and the second visit will assess the success of the intervention. The time burden for each manager interview visit is estimated as 20 minutes per response (18 annual hours). For the intervention group, educational intervention will be provided at the first visit, this is to inform restaurant managers about the risks posed by ill food workers and to help restaurants develop enhanced ill worker management plans. At this time, a short survey will be administered to food workers that are present at the time of the visit. It is estimated that on average there will be 5 food workers willing to participate at each restaurant and the survey should take no longer than 5 minutes (23 annualized hours). In the second visit; the manager interview and food worker surveys will be repeated, incurring similar burden hours as described above.

For the control restaurants, they will have a maximum of three site visits. In the initial visit, baseline manager interviews (18 annualized hours) and food worker surveys (23 annualized hours) will be conducted, but without the introduction of the educational intervention. If the intervention is successful, it will be introduced to the control restaurants during the second site visit, and the third site visit will be conducted with the same assessments as conducted previously to see if a change has occurred. The burden hours for each subsequent visit will be similar to the initial visit.

Supporting Statement Part A

The health department data collectors will also conduct up to three observational visits to examine the restaurant environment which will take approximately 30 minutes at each visit. These will be conducted at both intervention and control restaurants. These observations will not require interactions between the study personnel and restaurant staff and is estimated to be 27 annualized burden hours per each visit for each group. (See Table A.12-1).

Table 12.1- Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Restaurant Managers (Intervention and Control Restaurants)	Manager Recruiting Script	237	1	3/60	12
Restaurant Managers (Intervention Restaurants) Visit 1	Manager Informed Consent and Interview Form	54	1	20/60	18
Restaurant Managers (Intervention Restaurants) Visit 2	Manager Informed Consent and Interview Form	54	1	20/60	18
Food Workers (Intervention Restaurants) Visit 1	Food Worker Informed Consent and Survey	270	1	5/60	23
Food Workers (Intervention Restaurants) Visit 2	Food Worker Informed Consent and Survey	270	1	5/60	23
Health Department Workers (Intervention Restaurants) Visit 1	Restaurant Environment Observation Form	54	1	30/60	27
Health Department Workers (Intervention Restaurants) Visit 2	Restaurant Environment Observation Form	54	1	30/60	27
Restaurant Managers (Control Restaurants)	Manager Informed Consent and Interview	54	1	20/60	18

Supporting Statement Part A

Visit 1	Form				
Restaurant Managers (Control Restaurants) Visit 2	Manager Informed Consent and Interview Form	54	1	20/60	18
Restaurant Managers (Control Restaurants) Visit 3	Manager Informed Consent and Interview Form	54	1	20/60	18
Food Workers (Control Restaurants) Visit 1	Food Worker Informed Consent and Survey	270	1	5/60	23
Food Workers (Control Restaurants) Visit 2	Food Worker Informed Consent and Survey	270	1	5/60	23
Food Workers (Control Restaurants) Visit 3	Food Worker Informed Consent and Survey	270	1	5/60	23
Health Department Workers (Control Restaurants) Visit 1	Restaurant Environment Observation Form	54	1	30/60	27
Health Department Workers (Control Restaurants) Visit 2	Restaurant Environment Observation Form	54	1	30/60	27
Health Department Workers (Control Restaurants) Visit 3	Restaurant Environment Observation Form	54	1	30/60	27
Total					352

The maximum total annualized cost of this data collection to respondents is estimated to be \$5,333.22 (See Table 12-2). This figure is based on an estimated mean hourly wage of \$16.02 for managers and \$10.60 for food workers and \$19.80 for health department workers. These estimated hourly wages were obtained from the U.S. Department of Labor Bureau of Labor Statistics 2015 national occupational employment and wage estimates report (<http://stats.bls.gov/oes/current/oes351012.htm>; <http://stats.bls.gov/oes/current/oes352021.htm>).

12.2- Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent
---------------------------	---------------------------	-------------------------	-------------------------

Supporting Statement Part A

			Costs
Managers	90	\$16.02	\$ 1,441.80
Food Workers	115	\$10.60	\$1,219.00
HD Workers	135	\$19.80	\$2,673.00
Total			\$5,333.22

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Federal Government

Costs to the government include a portion of the annual cooperative agreement to the EHS-Net sites that will collect the data and the costs of CDC personnel working on the data collection (A.14.1). The sites participating in this study receive equal funding, and we estimate that the sites will use approximately 20% of their cooperative agreement funds to conduct this data collection. We also estimate that one CDC staff member will spend approximately 50% of their time on this data collection.

Table 14.1-Estimated Annualized Cost to the Federal Government

Expenditure	Cost
Awards to sites	\$102,667
CDC Salary (1 staff member)	\$16,667
Total	\$119,333

15. Explanation for Program Changes or Adjustments

This is a new data collection associated with an existing generic clearance.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 16.1 provides the data collection activity schedule.

16.1 – Project Time Schedule

Activity	Time Frame
Train EHS-Net sites on data collection	Within 1 month of OMB approval
Recruitment of restaurants	Within 3 months of OMB approval
Initial data collection	Within 6 months of OMB approval
Follow up data collection	Within 18 months of OMB approval
Follow up data collection (if needed)	Within 30 months of OMB approval
Data entry and quality assurance	Within 36 months of OMB approval
Data cleaning	Within 42 months of OMB approval
Data analysis	Within 48 months of OMB approval
Manuscript development	Within 60 months of OMB approval

Supporting Statement Part A

A detailed analysis plan can be found in Supporting Statement B (B.4).

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not requesting an exemption to the display of the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification for Paperwork Reduction Act.

Supporting Statement Part A

References for Part A

Sumner, S., Brown, L., Frick, R., Stone, C., Carpenter, L. R., Bushnell, L., . . . Everstine, K. (2011). Factors Associated with Food Workers Working while Experiencing Vomiting or Diarrhea. *J Food Prot*, 74(2), 215-220. doi:10.4315/0362-028x.jfp-10-108