

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

Revision

OMB No. 0920-0792
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Supporting Statement - A

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- Attachment 1 – Authorizing Legislation
- Attachment 2 – 60 Day Federal Register Notice
- Attachment 3a – NCEH-ATSDR Research Determination Form
- Attachment 3b- Privacy Impact Assessment
- Attachment 4 – EHS-Net Publications
- Attachment 5 – EHS-Net Manager Recruiting Script
- Attachment 6 – EHS-Net Manager Informed Consent
- Attachment 7 – EHS-Net Manager Interview
- Attachment 8 – EHS-Net Food Worker Recruiting Screener, Consent and Interview
- Attachment 9 – EHS-Net Restaurant Observation

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Goal of the study: The goal of this food safety research program is to collect data in retail food establishments that will identify and help to understand environmental factors (e.g. manager food safety certification, implementation of food safety practices, etc.) associated with retail-related foodborne illness and outbreaks.

Intended use of the resulting data: 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.

Methods to be used to collect data: Data will be collected through interviews or pen-and-paper assessments; and observations in random samples of food establishments in the EHS-Net-funded state and local food safety programs.

Subpopulation to be studied: The population to be studied will be randomly sampled voluntarily participating restaurants in the Environmental Health Specialists Network catchment area (which is currently comprised of: Minnesota; New York City; New York; Tennessee; Rhode Island; California; Southern Nevada Health District; and Harris County, Texas).

How data will be analyzed: Initial analyses will typically involve descriptive analyses and tests for association. Additional logistic or multivariable regression will be performed where appropriate.

Part A. Justification

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A.1. Circumstances Making the Collection of Information Necessary

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), is requesting a three-year Paperwork Reduction Act (PRA) approval for the revision Generic Information Collection (Generic ICR) titled, Environmental Health Specialists (EHS-Net) Program (OMB No. 0920-0792; OMB Exp. Date: 9/30/2018). The EHS-Net program, developed by CDC, conducts 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 outbreaks and food safety-associated events. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1). PRA revision approval for this impactful information collection needs to be in place prior to expiration in 09/30/2018.

The current request for PRA clearance is a revision, which involves some modifications to the Generic ICR. Overall, the number of respondents and burden hours have been increased to allow for additional statistical designs or to gather additional food worker responses per establishment. Details of the revision are described below:

- 1) The number of restaurants per site (8 EHS-Net sites, continues to remain the same) has been increased from 47 to 50 restaurants (totaling 400 restaurants); the sample size was increased to detect a greater odds ratio and establish a stronger power.
- 2) Data collected from additional food workers (increased to 10 food workers per restaurant from 1 food worker per restaurant, totaling 4,000 food workers) to help minimize the potential bias of only having one worker represent all of food workers in a given establishment. Additionally, going forward the restaurant observation data collection by the health department (HD) staff will also be accounted in the burden table. The HD staff are compensated for their time through a cooperative agreement (EH15-001), therefore the HD staff burden hours will not be reflected in the annualized burden costs; this is reflected in the annualized costs to the federal government.
- 3) Overall, for the duration of the next PRA cycle, we expect to conduct 2–3 studies depending on availability of resources. Therefore, due to an increase in the number of restaurants, food workers interviews and addition of restaurant observation activity the estimated annual burden hours are expected to increase from 295 to 1,777 hours.

EHS-Net is a collaborative project of the CDC, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and eight state and local public health departments (currently consisting of California, Minnesota, New York, New York City, Rhode Island, Tennessee, Southern Nevada Health District, and Harris County, Texas; however the sites may change with the re-issuance of the cooperative agreement at the end of its term). The EHS-Net sites are funded through CDC cooperative agreement EH15-001. EHS-Net's funding to these

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state and local health departments enables them to collaborate with CDC on study design, and data collection and analysis. The federal partners provide funding and input into study design, data analysis, and ensuring that research is not overlapping with their own studies.

Foodborne illness is a significant problem in the U.S.—an estimated 48 million cases of domestically acquired foodborne illness in the United States annually, resulting in over 127,000 hospitalizations and, over 3,000 deaths (Scallan, Griffin, Angulo, Tauxe, & Hoekstra, 2011; Scallan, Hoekstra, et al., 2011). Angulo (2006) reported that over 50% of the reported foodborne outbreaks are attributable to restaurants, making an understanding of the practices implemented in these establishments critical to preventing future cases of foodborne illness. Reducing foodborne illness requires identification and understanding of the environmental factors that allow these illnesses to occur – we need to know how and why the food becomes contaminated.

Environmental factors associated with foodborne illness include both food safety practices (e.g., inadequate cleaning practices) and the factors in the environment associated with those practices (e.g. worker and retail food establishment characteristics). To understand these factors, we need to collect data from those who prepare food (i.e., food workers) and on the environments in which the food is prepared (i.e. retail food establishment kitchens). Each EHS-Net GenIC will be a onetime data collection with a well-defined scope and objectives. Data collection methods for this generic package include: 1) screener, 2) manager and food worker interviews/information collection instruments (Attachments 7 and 9), and 3) observation of restaurant (Attachment 10). Both methods allow data collection on complementary aspects of the food safety practices and environmental factors associated with those practices.

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 studies can be used to understand the inter-relationship between existing intervention strategies (e.g. development of procedures and training) and food safety performance. It can also be used to understand current implementation practices of food safety provisions. This knowledge will allow for the development of future interventions that may have a higher efficacy in improving food safety practices.

The 60-day Federal Register Notice was published on 04/17/2018 (Attachment 2) and is further discussed in Section A.8.

A.2. Purpose and Use of the Information Collection

The purpose of the information collection is to gather data that will help us identify and understand environmental factors associated with foodborne illness. Specifically, the information will be used to:

- Describe retail food establishment food handling and food safety practices and manager/food worker and establishment characteristics,
- Determine how retail food establishment and food worker characteristics are related to food handling and food safety practices.

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The data will be used to enable CDC to develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry. For example, if an EHS-Net research project identifies an unsafe food handling practice or an environmental factor associated with an unsafe food handling practice, CDC can develop food safety recommendations addressing it. In turn, environmental public health regulatory programs and the food industry can take action to address the recommendation. This process will lead to increased food safety regulatory program effectiveness, increased industry effectiveness, increased food safety, and decreased foodborne illness.

In October 2008, OMB approved the generic information collection to CDC for the EHS-Net program. This collection request has been continued in both 2012 and 2015.

To date, EHS-Net has had five genICs approved under this generic clearance:

1) Title: Food Cooling Practice Study

Study population: Managers and establishments' food safety practices in 420 restaurants

Key findings: This study collected data on improper cooling of hot foods, a food handling practice associated with foodborne illness and outbreaks, and found many restaurants do not follow Food and Drug Administration (FDA) cooling advice. Foods not being actively monitored by food workers were more than twice as likely to cool more slowly than recommended in the Food Code guideline. Food stored at a depth greater than 7.6 cm (3 in.) was twice as likely to cool more slowly than specified in the Food Code guideline. Unventilated cooling foods were almost twice as likely to cool more slowly than specified in the Food Code guideline. The data suggests that several best cooling practices can contribute to a proper cooling process. Inspectors unable to assess the full cooling process should consider assessing specific cooling practices as an alternative. Future research could validate this estimation method and study the effect of specific practices on the full cooling process.

2) Title: Restaurant Manager and Worker Food Safety Certification Study

Study population: Managers, food workers and establishments' food safety practices in 390 restaurants

Key findings: This study collected data on the relationship between kitchen manager food safety certification and foodborne illness risk factors in restaurants. Public health agencies are increasingly encouraging or requiring certification as a foodborne illness prevention measure, yet little was known about its effectiveness. Data from this study found that having a Certified Food Protection Manager was associated with a decreased number of critical food safety violations. Other factors associated with greater food safety knowledge included working in a chain restaurant, working in a larger restaurant, having more experience, and having more duties. These findings indicate that certification improves food safety knowledge, and that complex relationships exist among restaurant, manager, and worker characteristics and food safety knowledge.

3) Title: Retail Deli Food Safety Practices Study

Study population: Managers, food workers and establishments' food safety practices in 298 delis

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Key findings: This study collected data on the environmental factors associated with contamination of the retail deli environment with *Listeria*, a foodborne illness pathogen ranked 3rd in terms of the number of deaths it causes. More than half of the retail delis did not fully clean their food slicers as often as Food and Drug Administration recommends (every 4 hours) to prevent the spread of *Listeria* and other germs that cause foodborne illness. Deli ownership, deli size, manager and food worker safety knowledge, training, and certification, written slicer-cleaning policies, and easy-to-clean deli slicers are each associated with slicers being cleaned more often.

4) Title: Food Allergens Practices Study

Study population: Managers, food workers, and servers in 278 restaurants

Key findings: This study collected data on manager, food worker, and server knowledge and attitudes about food allergies to identify practices to reduce the risk of food allergic reactions in restaurants. Results indicated that managers, food workers, and servers were generally knowledgeable and had positive attitudes about accommodating customers' food allergies. However, important gaps were identified, such as more than 10% of managers and staff believed that a person with a food allergy can safely consume a small amount of that allergen. Managers and staff also had lower confidence in their restaurant's ability to properly respond to a food allergy emergency. The knowledge and attitudes of all groups were higher at restaurants that had a specific person to answer food allergy questions and requests or a plan for answering questions from food allergic customers. The data suggests that most restaurants could do more to reduce the risk of allergic reactions as food allergens training was not comprehensive and most restaurants did not have dedicated areas and equipment for preparing and cooking allergen-free food.

5) Title: Food Safety Practices and Beliefs Study

Study population: Managers, food workers and establishments' food safety practices in 376 restaurants

Key findings: EHS-Net study is ongoing

To date, EHS-Net has summarized its research efforts in 30 publications (Attachment 4), and has presented its research findings at numerous conferences. Also, CDC and FDA used EHS-Net research to support a change to the 2017 FDA Food Code that requires restaurants to have a Certified Food Protection Manager present during all hours of operation. State and local food codes are based on the FDA Food Code; thus, this change is significant and influential.

Data will be collected by environmental health specialists in participating EHS-Net sites. The EHS-Net study population is retail food establishments in selected geographical areas, as stated in section A.1. While the number of areas included in EHS-Net 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 in the individual studies for ensuring a representative sample in the study are used, the results of the collection can be used to generalize to the population of retail food establishments in the given EHS-Net site(s).

A.3. Use of Improved Information Technology and Burden Reduction

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Most EHS-Net data collections will involve face-to-face interviews with respondents and electronic data collections (depending on availability of resources). Respondents will provide their responses verbally to interviewers. Verbal responses, compared to typed or handwritten responses, are easier for the majority of respondents to provide. In some cases, data collections may also involve a short pen-an-paper assessment or short web-based surveys. An example would be a food safety knowledge assessment. In these cases, we would ensure that the required written response is easy and simple- circling an answer choice, for example.

Participation in the EHS-Net data collections is **voluntary**, and every effort will be made to keep the data collection as short as possible and still meet the needs of the data collection.

A.4. Efforts to Identify Duplication and Use of Similar Information

EHS-Net strives to ensure that the data collections proposed are not a duplication of effort. We search relevant scientific bibliographical databases (e.g., PubMed, Ovid, Agricola), attend national meetings (e.g., National Environmental Health Association, International Association of Food Protection), and consult with other organizations (e.g., FDA, USDA-FSIS) concerning research on the proposed topics. We have determined that there is little high quality data available on retail food worker and establishment characteristics combined with food handling and food safety practices. However, prior to designing each data collection, we will conduct a comprehensive review of the scientific literature to determine if data already exist on the specific topic of interest.

A.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 the data collections. Short forms for small businesses will not be developed. Both large and small businesses will be presented with the same questions, and the results will be assessed for differences by various restaurant characteristics (e.g. seating capacity, number of food service workers, level of foodhandling, etc.). We will, however, strive to hold the number of questions to the minimum needed for the intended use of the data.

A.6. Consequences of Collecting the Information Less Frequently

Respondents will be asked to respond to each data collection only one time. 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 environmental factors that are associated with foodborne illness. In turn, it will be more difficult to decrease the number of incidents of foodborne illness caused by these factors 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.

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

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

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

- A. The 60-day *Federal Register* notice was published on 04/17/2018 in vol. 83, no. 74, page no. 16860 (Attachment 2). No comments were received in response to the 60-day federal register notice.
- B. Consultation with staff from EHS-Net participant sites, CDC centers, and federal agencies will occur in preparation for and in conjunction with the fielding of data collections under this request. Table 8.1 lists the current individuals that will be consulted. The officials identified under EHS-Net sites is comprised of epidemiology and environmental health professionals from each of the participating sites. These individuals have been actively involved in in the identification, prioritization, development, and implementation of data collection activities in the past and we anticipate their ongoing support to play a similar role in the future. This list may change in the future as individuals take on new roles or change positions.

8.1 List of Individuals Consulted on Studies

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2016-2020 EHS-Net Sites (Currently participating 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@hcuphes.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	Kristin Holt, DVM USDA/FSIS Liaison CDC/OID/NCEZID krh7@cdc.gov 404-639-3379
Arthur Liang, MD, MPH Director, Food Safety Initiative CDC/OID/NCEZID apl1@cdc.gov 404-639-2237	

A.9. Explanation of Any Payment or Gift to Respondents

There will be no payments or gifts to respondents.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act does not apply to projects performed under this collection; however, all proposed projects will be reviewed by the NCEH Information Systems Security Officer (ISSO) for a determination. Since the Privacy Act does not apply, 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

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participating restaurants or staff from the EHS-Net sites. The NCEH Human Subjects Contact has reviewed the information collected under this Generic ICR has classified this as human subjects research, but CDC is not engaged (Attachment 3a). Therefore, CDC's Institutional Review Board (IRB) approval is not required. However, EHS-Net sites will obtain approval from their respective IRBs as appropriate.

Information in identifying form (IIF) about individuals is not collected in this ICR. Address information pertaining to restaurants is collected to allow site visits. Subsequent to the site visit, the restaurant name and address will no longer be needed and will be destroyed by the sites. The individual EHS-Net sites will assign a code number to the restaurant and only that code number will be reported to CDC approved software system (Attachment 3b) Research Electronic Data Capture (REDCap). Each site will delete any electronic keys or shred paper keys. If REDCap is not operational or feasible for data collection, other data systems will be utilized.

No paper files will be delivered to CDC. Instead, data collectors will enter all paper-and-pencil responses into the REDCap. Data will be reported to CDC through a web-based information system. All electronic data will be stored on secure CDC networks. Access to the data will be to the discretion of CDC. 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. 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. Each site's data will be stored for twelve years.

Verbal consent will be obtained from respondents. 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. Attachments 6–10 provide a sample of the data collection forms and informed consent statements. 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.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

No information will be collected that is of a sensitive or personal nature.

12. Estimates of Annualized Burden Hours and Costs

For each project under this collection, we anticipate collecting data in approximately 50 restaurants per site. Thus, there will be approximately 400 restaurants per site (8 EHS-Net sites*50 restaurants). We anticipate a manager/restaurant recruitment rate of approximately 45%; thus, we will need to contact 889 restaurant managers via telephone in order to meet our goal of 400 respondents (Attachment 5 contains a sample telephone manager recruiting script). Each respondent to the script will respond only once, and the average burden per response will be approximately 3 minutes (44 annual burden hours.)

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In restaurants that voluntarily agree to participate in this study, we will interview the manager about the restaurant’s characteristics and existing food safety procedures and practices (Attachment 7 has a sample interview form.) It is estimated that this will take approximately 30 minutes (200 annual burden hours). Following this, food worker(s) will be recruited from the restaurant for participation in either a semi-structured interview or structured written/electronic survey (Attachment 8). We anticipate recruiting maximum 10 food service workers per restaurant with an estimated burden time of 20 minutes per respondent (1333 annual burden hours); some restaurants will have less than 10 food service workers at the time of site visit, providing a conservative estimate of the annual burden hours for food service workers in Table 12.1. The EHS-Net data collectors, from various health departments, will complete the restaurant observation form (Attachment 9) documenting practices and infrastructure in the restaurant related to food safety. These observations will require interactions between the data collectors (HD staff) and managers, and is estimated to take approximately 30 minutes (200 annual burden hours). The HD staff are compensated for their time through a cooperative agreement (EH15-001), therefore the HD staff burden hours will not be reflected in the annualized burden costs in Table 12.2; this is reflected in the annualized costs to the federal government (awards to sites) in Table 14.1. For the specific study designs, we will assess the number of respondents and time necessary and strive to minimize the burden, when possible. We have provided conservative estimates in Tables 12.1 and 12.2, as a data collection study would not occur on an annual basis; we expect to conduct two (three maximum) data collections during a three-year PRA cycle.

12.1- Estimated Annualized Burden Hours

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Managers	EHS-Net Manager Recruiting Script	889	1	3/60	44
Managers	EHS-Net Manager Informed Consent and Interview	400	1	30/60	200
Food Workers	EHS-Net Food Worker Recruiting Screener, Consent, and Interview	4,000	1	20/60	1,333
HD staff	EHS-Net Restaurant Observation	400	1	30/60	200
TOTAL					1,777

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The maximum total annualized cost of this data collection to respondents is estimated to be \$18,759.58 (See Table 12.2). This figure is based on an estimated mean hourly wage of \$16.68 for managers and \$11.02 for food workers. These estimated hourly wages were obtained from the U.S. Department of Labor Bureau of Labor Statistics 2016 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 Costs
Managers	244	\$16.68	\$4,069.92
Food Workers	67	\$11.02	\$14,689.66
Total			\$18,759.58

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 (Table 14.1). The EHS-Net 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 two CDC staff members will spend approximately 50% of their time on this data collection.

14.1- Estimated Annualized Cost to the Federal Government

Expenditure	Cost
Awards to sites (\$192,500 * 8 sites)	\$1,540,000
CDC Salary (50% of 2 staff members)	\$150,000
FOA administration	\$150,000
Travel for site visits	\$5,000
Total	\$1,845,000

15. Explanation for Program Changes or Adjustments

This is a revision of the generic information collection request that is set to expire in September 2018. The current package differs from the previous package in the following ways, described below:

Based upon the feedback from previous studies, the number of respondents and burden hours has been increased to allow for additional statistical designs or to gather additional food worker responses per establishment. The number of restaurants per site (8 EHS-Net sites, which has remained the same) has been increased from 47 to 50 restaurants (totaling 400 restaurants); the

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sample size was increased to detect a greater odds ratio and establish a stronger power. Collecting data from additional food workers (increased to 10 food workers per restaurant from 1 food worker per restaurant, totaling 4,000 food workers) will help minimize the potential bias of only having one worker represent all of food workers in a given establishment. Additionally, going forward the restaurant observation data collection activity (previously not included) by the health department (HD) staff will also be accounted in the burden table.

Overall, for the duration of the next PRA cycle, we expect to conduct 2–3 studies depending on availability of resources. Therefore, due to an increase in the number of restaurants, food workers interviews and addition of restaurant observation activity the estimated annual burden hours are expected to increase from 295 to 1,777 annual hours. The estimated annual cost to the federal government is expected to marginally decrease in the current cycle to \$1,845,000 from \$2,223,500 due to internal program adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 16.1 provides a model schedule of the data collection activities expected to occur with each study.

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 2 months of OMB approval
Data collection	Within 10 months of OMB approval
Data entry and quality assurance	Within 12 months of OMB approval
Data cleaning	Within 18 months of OMB approval
Data analysis	Within 22 months of OMB approval
Manuscript development	Within 24 months of OMB approval

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.

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References for Part A

- Angulo, F. J., & Jones, T. F. (2006). Eating in Restaurants: A Risk Factor for Foodborne Disease? *Clinical Infectious Diseases*, 43(10), 1324-1328. doi:10.1086/508540
- Scallan, E., Griffin, P. M., Angulo, F. J., Tauxe, R. V., & Hoekstra, R. M. (2011). Foodborne illness acquired in the United States--unspecified agents. *Emerg Infect Dis*, 17(1), 16-22. doi:10.3201/eid1701.091101p2
- Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., . . . Griffin, P. M. (2011). Foodborne illness acquired in the United States--major pathogens. *Emerg Infect Dis*, 17(1), 7-15. doi:10.3201/eid1701.091101p1