Public Health Ethics Activities at State and Local Health Departments: Current Status and Challenges

OSTLTS Generic Information Collection Request OMB No. 0920-0879

Supporting Statement - Section A

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Table of Contents

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

- Purpose of the data collection: CDC's Public Health Ethics Unit works to support Public Health Ethics Activities at state and local health departments. The proposed information collection will help the Public Health Ethics Unit assess current state and local health department practices regarding ethics and barriers to implementing public health ethics activities, determine what resources health departments need to improve or establish formal public health ethics processes, and provide insights into ways in which health departments might evaluate the impact of a formal public health ethics process.
- Intended use of the resulting data: The information collected will help the Public Health Ethics Unit refine existing guidance as well as develop additional resources to support state and local health departments in their efforts to build ethics infrastructure.
- **Methods to be used to collect data:** Data will be collected using an online survey and a followup telephone interview with a subset of survey respondents.
- **Respondent universe:** The respondent universe for this information collection consists of 80 state and local health directors (or their designated representative). This includes health directors from all 50 states and the 30 local health departments in the Big Cities Health Coalition. A subset (n=8) of the 80 respondents who participated in the online survey will be invited to participate in an individual telephone interview.
- **How data will be analyzed:** The data will be analyzed using descriptive statistics and qualitative methods. Comparisons will be made between state and local health departments and between accredited and non-accredited health departments.

Section A - Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from a total of 80 health department directors (or their designated representative). Fifty of the respondents will be from state health departments, and 30 respondents will be from local health departments that are members of the Big Cities Health Coalition (for list of BCHC members, see **Attachment A—List of Big City Health Coalition Members**). Eight of the online respondents will be purposively selected for a follow-up telephone interview. All respondents will be acting in their official capacities.

U.S.C. 241). This information collection falls under the essential public health service(s) of
1. Monitoring health status to identify community health problems
2. Diagnosing and investigating health problems and health hazards in the community
3. Informing, educating, and empowering people about health issues
4. Mobilizing community partnerships to identify and solve health problems
5. Development of policies and plans that support individual and community health efforts
6. Enforcement of laws and regulations that protect health and ensure safety
7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
8. Assuring a competent public health and personal health care workforce
9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
10. Research for new insights and innovative solutions to health problems¹¹

This information collection is authorized by Section 301 of the Public Health Service Act (42)

Public health ethics involves a systematic process to clarify, prioritize and justify possible courses of public health action based on ethical principles, values and beliefs of stakeholders, and scientific and other information. The field of public health ethics is relatively young, growing out of its historical underpinnings in clinical, biomedical, and research ethics. The practice of public health ethics involves applying not only the traditional ethical principles of beneficence, autonomy, and non-maleficence, but also reaches beyond a focus on individual health into promoting social justice, solidarity, and increased health equity among populations.

State and local health officials stand on the frontline of decision making to promote the health and well-being of the population. In their everyday activities, public health officials grapple with decisions that present ethical challenges such as allocating scarce resources and respecting individual rights while protecting the public good. In 2009, the Presidential Commission for the Study of Bioethical Issues, which advised the President of the United States on bioethical issues, recognized that there was a need to provide local decision makers with tools to integrate ethics into decision making at all levels. Despite the Commission's recognition, there is still a lack of ethics resources and education available to public health departments.

The Association of Schools and Programs of Public Health (ASPPH) also recognized the need for public health ethics training in public health school curricula. ASPPH lists ethical standards in several of its required competencies for U.S. public health graduates. iii However, only half of the accredited schools of public health require coursework that would help students acquire the competencies required to address ethical challenges. iv

In order to provide much needed ethics support, the Public Health Ethics Unit at the Centers for Disease Control and Prevention (CDC) offers training and guidance to help health departments integrate public health ethics into their decision-making processes. The Public Health Ethics Unit has worked with the National Association of County and City Health Officials (NACCHO) to

assist local health departments in their efforts to build ethics capacity and integrate a framework for ethical analysis into day-to-day operations.

The Public Health Ethics Unit's work also supports health departments' efforts to receive accreditation through the Public Health Accreditation Board (PHAB). PHAB administers a voluntary national accreditation program that seeks to improve and protect the health of the public by advancing the quality and performance of health departments. In December 2013, PHAB revised its "Standards & Measures" criteria to include several new elements including an ethics measure. The inclusion of ethics in the accreditation process highlights the importance of ethical decision-making in the practice of public health.

With the addition of the accreditation measure related to public health ethics in version 1.5 of the Standards & Measures criteria, more health departments are working to create ethics infrastructure. Two notable examples of early adopters of a formal ethics process include local health departments in Clark County, Washington and Mahoning County, Ohio. The Clark County Public Health Department (CCPH) ethics committee began deliberating issues in 2012. VI During that time the committee has deliberated issues ranging from whether public health officials should receive gifts from pharmaceutical companies to whether CCPH should participate in a federal Nurse Family Partnership study that randomized participants. VIII The committee utilizes a framework for ethical decision making to guide their analyses of local public health issues and provides a consistent method to integrate ethics into all of the department's public health activities. VIII This framework for ethical analysis allows CCPH to justify decisions and provides transparency and accountability to CCPH staff, management, and community partners.

The Mahoning County District Board of Health Ethics Advisory Committee (EAC) assists the Board of Health and staff in making ethical decisions. The EAC operates under the Mahoning County Code of Public Health Ethics. ^{ix} The Code of Public Health Ethics helps to facilitate ethical decision making by the department, and the EAC works to ensure that individuals may freely express their ethical and professional concerns. The EAC seeks to have wide representation. Therefore, it is composed of members of the Board of Health, public health practitioners, community members, and representatives of relevant professions. This inclusive approach provides the Board with multiple viewpoints on the issues that the committee discusses. The EAC practices transparency by making their meeting minutes public in order to build trust in the community.^x

Other health departments are also working to build ethics infrastructure, however, there is not complete information about where most health departments are at in this process. Therefore, the purpose of this data collection is to reach out to all 50 state health departments and the 30 health directors from the Big Cities Health Coalition (BCHC), assess current state and local health department practices regarding ethics and barriers to implementing public health ethics activities, identify what resources health departments need to improve or establish formal public health ethics processes, and provide insight into ways in which health departments might evaluate the impact of a formal public health ethics process.

The results from this information collection will be used by CDC's Public Health Ethics Unit to develop more effective trainings and guidance for health departments and support health department's efforts to integrate public health ethics into their decision-making processes. The improved training and guidance will also support health department efforts to meet the new ethics measure incorporated into the PHAB 1.5 accreditation criteria.

Overview of the Information Collection System

NACCHO estimates that there are approximately 28,000 local health departments. The data collection will focus on a subset of local health directors. Data will be collected from a total of 80 health department directors (or their designated representative). Fifty of the respondents will be from state health departments, and 30 respondents will be from local health departments that are members of the Big Cities Health Coalition (for list of BCHC members, see **Attachment A— List of Big City Health Coalition**Members). Eight of the online respondents will be purposively selected for a follow-up telephone interview. All respondents will be acting in their official capacities.

Names, email addresses, and telephone numbers of health directors will be obtained from the records of the CDC Office of State, Tribal, Local and Territorial Support (OSTLTS) and from the Big City Health Coalition. In addition, we will ask OSTLTS to supply information about the size of the population served and governance structure of the health department.

Data will be collected via two methods: An online survey administered via Survey Monkey (see Attachment B- Online Survey Instrument: Word Version and Attachment C— Online Survey Instrument: Web version) and a follow-up telephone interview (see Attachment D— Telephone Interview Guide). On March 6, 2018, the Office of the Chief Information Officer approved the "Third-Party Site Security Plan" for use of Survey Monkey for administration of the online survey.

During the instrument development phase, we received input on the online survey from five public health professionals. This included four NACCHO staff members (including experts in research and evaluation), one current local health director, one retired local health director, and one official from the Big City Health Coalition. Their input was used to refine the questions and improve their relevancy for state and local health directors. To estimate the time required to complete the online survey, it was pilot tested by four public health professionals, including two current local health directors, one retired local health director, and a retired CDC health official who also had previous experience in a state health department. Two of these four had provided input during the development of the online survey.

We received input on the telephone interview guide from four public health professionals. This included two NACCHO staff members, a current local health director, and a retired local health director. All four of these had provided input on the online survey. Their input was used to ensure that we would be asking the most relevant questions and expanding upon information

collected by the online survey. Because of our intent to limit the telephone interview to 60 minutes, we did not pilot test the telephone interview questions.

Items of Information to be Collected

Online Survey

The online survey data collection instrument (see **Attachment B- Online Survey Instrument: Word Version** and **Attachment C— Online Survey Instrument: Web version**) consists of 33 questions of various types, including dichotomous (yes/no/unsure), check all that apply, rating scales, and open-ended questions. While developing the survey instrument an effort was made to limit questions requiring narrative responses.

The following categories of questions were asked:

- Section 1 Background information (3 questions)
- Section 2 Current ethics activities (18 questions)
- Section 3 Needs assessment (9 questions)
- Section 4 Impact of public health ethics activities (3 questions)

Depending on skip patterns, respondents may be asked as few as 16 questions and as many as 33 questions.

Telephone Interviews

The telephone interview guide (see **Attachment D— Telephone Interview Guide**) will be used to obtain more detailed information on the topics covered in the online survey. The interview will be guided by 38 prompts that will be used to facilitate open-ended responses. While we have developed written questions, the interview is not intended to be a scripted interview. Our intent is that our questions lead to a focused discussion about each health department's public health ethics activities, needs related to public health ethics resources, and perceptions of the impact of implementing public health ethics activities. In order to avoid overly burdening the respondents, we will limit the telephone interview to 60 minutes.

The following categories of questions will be asked:

- Focus Area 1 Current ethics activities (27 prompts)
- Focus Area 2 Needs (4 prompts)
- Focus Area 3 Resources for measuring impact (4 prompts)
- Closing Questions (3 questions)

Depending on responses to the online survey, as few as 19 and as many as 34 prompts will be applicable per individual telephone interview respondent.

2. Purpose and Use of the Information Collection

The purpose of this data collection is to assess current state and local health department practices regarding ethics and barriers to implementing public health ethics activities, identify what resources health departments need to improve or establish formal public health ethics processes and provide insight into ways in which health departments might evaluate the impact of a formal public health ethics process.

The results from this information collection will be used by CDC's Public Health Ethics Unit to develop more effective trainings and guidance for health departments and support health department's efforts to integrate public health ethics into their decision-making processes. The improved training and guidance will also support health department efforts to meet the new ethics measure incorporated into the PHAB 1.5 accreditation criteria. Long term, the information collected will assist in the Public Health Ethics Unit's efforts to develop guidance on best practices for assessing the impact of a public health ethics activity.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via two methods: online survey and telephone interviews.

Online Survey

An online survey method was chosen to because it allows respondents to complete and submit their responses electronically, reducing the overall burden on respondents. This information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 33 questions). Also, skip patterns were incorporated to allow for streamlining responses, further reducing overall burden on respondents.

Telephone Interviews

The telephone interview will be conducted on a subset of survey respondents who indicated that they would be interested in participating in the telephone interview. Telephone interviews can solicit rich qualitative data. Staff will be able to verify responses and request clarification in real time as needed during the information collection process. The telephone interview guide was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 34 questions). Embedded within the telephone interview guide are skip patterns which will customize the interview to respondent answers. Additionally, the telephone interview will be limited to 60 minutes, minimizing the overall burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

While there is information that describes the field of public health ethics and topics that raise ethics concerns relating to public health practice, the proposed data collection will examine specific public health ethics practices in state and local health departments.

For example, Nancy Baum has written about analytical frameworks for addressing ethical issues that arise in public health practice, but the discussion was theoretical in nature and no data were collected about how health departments actually handle ethics issues that arise in practice. **ii* Another article by Baum looked at the ethical challenges public health practitioners in Michigan face and identified the approaches that are being used to resolve those challenges. **Iii* In contrast to the data gathered for the Baum article, the proposed data collection will examine departmental approaches to public health ethics rather than individual approaches. The scope of the proposed data collection is also broader than the data collected for the Baum article. The proposed data collection will gather information from public health departments across the country about public health ethics training, departmental public health ethics needs, and possible methods for measuring the impact of formal public health ethics processes.

There have also been assessments that point to the need for additional ethics training for graduate students, xiv, xv however the proposed data collection will provide insights into public health ethics training for public health professionals working at state and local health departments. Since deficits in public health ethics education have been identified in graduate school curricula, it is important to learn more about the ethics training professionals receive once they enter the workforce.

In addition to articles that have examined public health ethics, the Public Health Accreditation Board (PHAB) also collects information about public health ethics practices as part of the accreditation process. **vi* PHAB administers a voluntary national accreditation program that seeks to improve and protect the health of the public by advancing the quality and performance of health departments. In December 2013, PHAB revised its accreditation criteria (Version 1.5) including added a new accreditation element regarding ethics capacity. **wii** . While the accreditation process gathers some information about public health ethics practices in state and local health departments, not all health departments are accredited and of the ones that are accredited, not all are accredited under PHAB Standards and Measures Version 1.5.

Another novel aspect of the proposed data collection are the questions about ways to measure the impact of a formal ethics process. Measuring the impact of a formal ethics process is an important component of justifying continued investment in public health ethics. Most state and local health departments operate in a resource-constrained environment. Therefore learning more about what data health departments use or could use to evaluate the impact of public health ethics will help to strengthen public health ethics process and programs.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Develop public health ethics training materials that are reflective of the needs identified by this data collection
- Develop guidance that addresses the barriers to developing a public health ethics program that are identified by the data collection
- Develop guidance related to measuring the impact of public health ethics practices

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

There are no special circumstances with this data collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on April 27, 2017, Vol. 82, No. 80, pp 19371-19373. One non-substantive comment was received. CDC sent forward the standard CDC response.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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

The Privacy Act does not apply to this data collection. State, Tribal, Local & Territorial (STLT) governmental staff and / or delegates will be speaking from their official roles. All information collected will be kept on secure, password protected servers accessible only to CDC project team members. No IIF will be distributed.

This data collection is not research involving human subjects. On November 21, 2017, the Human Research Protection Office determined that this project did not involve human subjects' research.

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

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

12. Estimates of Annualized Burden Hours and Costs

Online Survey

The estimate for burden hours is based on a pilot test of the online data collection instrument by 4 public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 8 minutes (range: 6 - 11 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 11 minutes) is used.

Telephone Interviews

In order to not unduly burden respondents, we will limit the time for the telephone interview to 60 minutes. Thus, we did not pilot test the data collection instrument for the telephone interview. The maximum burden for the data collection instrument, including reviewing instructions, gathering needed information and completing the instrument will be 60 minutes.

Estimates for the average hourly wage for all respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for medical and health service managers from http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of \$46.41 is estimated for all 88 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Data collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Online	Health	80	1	11/60	15	\$46.41	\$696.15
Survey	Department						
	Director or						
	Designee						

Telephone	Health						
Interview	Department	8 (of the 80)	1	60/60	8	\$46.41	\$371.28
	Director or						ψ3/1.20
	Designee						
	TOTALS	88			23 Hours		\$1067.43

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

There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff to develop the data collection instrument, collect data, perform data analysis, and disseminate the results. The total estimated cost to the federal government is \$28,243.29. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Lead, Public Health Ethics Unit– U.S. Public	312	\$45.00/hour	\$14,040.00
Health Service 06			
Project oversight, instrument development,			
data collection, data analysis, dissemination			
of results			
Senior Ethics Consultant – GS-13, Step 8;	15	\$54.15/hour	\$812.25
Instrument development, data collection, data			
analysis, dissemination of results			
Public Health Analyst – GS-12, Step 1;	312	\$36.92/hour	\$11,519.04
Project administration, instrument			
development, data collection, dissemination			
of results			
Research Assistant Project administration,	312	\$6.00/ hour	\$1,872.00
instrument development, data collection, data			
analysis, dissemination of results			
Estimated To	\$28,243.29		

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Information collected from the online survey will be stored in a secure environment maintained by the Public Health Ethics Unit. Once the survey is closed, responses will be downloaded from Survey Monkey into an Excel spreadsheet file. Data will be reviewed for completion and simple descriptive statistics will be run examining response frequencies. Depending on the response distribution, frequencies may be cross-tabulated to identify response similarities and differences between subgroups of respondents (e.g. state vs. local health departments, accredited vs non-accredited health departments).

All telephone interviews will be recorded and transcribed. Verbal permission to be recorded will be obtained from the participant prior to the beginning of the interview. Information from the telephone interviews will be stored in a secure environment maintained by the Public Health Ethics Unit. Each of the transcribed interviews will be compared against the recording to ensure accuracy. Thematic analysis will be used to analyze data. The qualitative software management program QDA Miner Lite will be used to code the interviews.

Following analysis of responses to all information collection instruments, key findings will be shared in aggregate form with project staff, partner organizations and the respondents who participated in this information collection. Additionally, staff at CDC will condense key findings from the online survey and telephone interviews, refine them into a manuscript format, and submit for publication in a scientific journal.

<u>Timeline for Data Collection</u> (Note: Days reflect business days)

Week 1 (Day 1) - Send Online Survey Invitation Email

Week 2 (Day 9) – Send Online Survey Reminder Email 1 to non-responders

Week 3 (Day 14) - Send Online Survey Reminder Email 2 to non-responders

Week 3 (Day 15) – Online survey closes

Week 4 (Days 16-19) – Review online survey results to identify candidates for the telephone survey

Week 4 (Day 20) - Select 8 participants for the telephone interview

Week 5 (Day 21) - Send Telephone Interview Invitation Email

Week 6 (Day 26) - Send Telephone Interview Reminder Email to non-responders

Week 6 (Day 28) – Contact alternates for telephone interviews if needed

Weeks 6-8 (Days 26-40) – Conduct 8 telephone interviews

Project Time Schedule

\checkmark	Design instrument	(COMPLETE)
\checkmark	Develop protocol, instructions, and analysis plan	(COMPLETE)
\checkmark	Pilot test instrument	(COMPLETE)
\checkmark	Prepare OMB package	(COMPLETE)
\checkmark	Submit OMB package	(COMPLETE)
	OMB approval	(TBD)

Conduct data collection via online survey	(3 weeks)
Conduct data collection via phone interview	(5 weeks)
Code data, conduct quality control, and analyze data	(3 months)
Prepare summary report(s)	(4 months)
Disseminate results/reports	(2 months)

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS - Section A

Note: Attachments are included as separate files as instructed.

- A. Attachment A— List of Big City Health Coalition Members
- B. Attachment B—Online Survey Instrument: Word Version
- C. Attachment C—Online Survey Instrument: Web version
- D. Attachment D—Telephone Interview Guide

REFERENCE LIST

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