

**Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics-**

**College of American Pathologists**

***Request for Approval of New Data Collection***

***Supporting Statement A***

**February 20, 2015**

**Contact:**

**Rex Astles, PhD**

**Division of Laboratory Programs, Standards, and Services**

**Center for Surveillance, Epidemiology, and Laboratory Services**

**Centers for Disease Control and Prevention**

**1600 Clifton Rd.**

**MS F-11**

**Atlanta, Georgia 30333**

**Phone: 404.498.2296**

**Fax: 404.498.2219**

**Email: [JAstles@cdc.gov](mailto:JAstles@cdc.gov)**

## Table of Contents

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

## **Appendices**

- Attachment A. Authorizing Legislation
- Attachment B. Published 60-Day Federal Register Notice
- Attachment C. IHC Post-Dissemination Survey Paper Copy
- Attachment D. ALA Baseline Survey Monkey Screen Shots
- Attachment E. Privacy Act Checklist
- Attachment F. IHC Communication Materials
- Attachment G. ALA Communication Materials
- Attachment H. IHC Pilot Survey Results
- Attachment I. ALA Pilot Survey Results
- Attachment J. Part I Worksheet
- Attachment K. Part II Worksheet- IHC Pathologists
- Attachment L. Part II Worksheet- IHC Laboratory Directors
- Attachment M. Part II Worksheet- IHC Laboratory Managers
- Attachment N. Part II Worksheet- ALA Pathologists
- Attachment O. Part II Worksheet- ALA Hematologists

- Goal of study: To explore factors that may influence intended users of laboratory practice guidelines (LPGs)
- Intended use of resulting data: The CAP can define and use metrics to better inform their LPGs' creation, revision, dissemination, promotion, uptake and use. The collected survey data will be analyzed to determine how immunohistochemistry (IHC) and acute leukemia algorithm (ALA) LPGs should be created/disseminated and promoted to address barriers observed with specific sub-groups of health professionals.
- Methods to be used to collect: A post-survey for an LPG that involves IHC testing and a separate pre-survey concerning a new LPG for ALA
- Subpopulations to be studied: Pathologists, hematologists and various laboratory professionals
- How data will be analyzed: Cohort study; pre- versus post-dissemination of LPGs

## **A. Justification**

### **1. Circumstances Making the Collection of Information Necessary**

#### **Background**

This is a request for OMB approval of a new information collection, “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics- College of American Pathologists.” CDC is requesting a one year approval to collect the information. This information collection falls under the Title 42 Public Health and Welfare Authorization Legislation included as Attachment A.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established minimum requirements for assuring the quality of laboratory testing in U.S. clinical laboratories. However, many laboratories voluntarily implement quality practices that go beyond the minimum standards required by CLIA regulation by identifying and adhering to relevant laboratory practice guidelines (LPGs). An “LPG” is defined as written recommendations for voluntary, standardized approaches for medical laboratory testing that takes into account processes for test selection, sample procurement and processing, analytical methods, and results reporting for effective diagnosis and management of disease and health conditions. LPGs may be disseminated to, and used by, laboratorians and clinicians to assist with test selection and test result interpretation.

The Centers for Disease Control and Prevention is funding three 5-year cooperative agreement projects collectively entitled “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics” under funding opportunity announcement number OE13-04. The overall purpose of these cooperative agreements is to increase the effectiveness of LPGs that have public health impact by defining measures and collecting information to inform better LPG creation, revision, dissemination, promotion, uptake, and impact on clinical testing and public health. The project will explore how these processes and their impediments and facilitators differ among various intended users of LPGs including: (1) non-laboratorians, (2) laboratorians, including medical laboratory technicians (2-year degree),

medical technologists (4-year bachelor degree, also called “clinical laboratory scientists” or “medical laboratory scientists”), clinical laboratory directors, supervisors, and managers of clinical laboratories, and pathologists; and, (3) clinicians, including physicians and nurses. Through this demonstration project, CDC seeks to understand how to customize LPG creation and promotion to better serve these intended users of LPGs. An important goal is to help organizations that sponsor the development of LPGs create a sustainable approach for continuous quality improvement to evaluate and improve an LPG’s impact through better collection of information.

After an objective review process to score applications to a new cooperative agreement funding opportunity, “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics,” the CDC selected three organizations that currently create and disseminate LPGs to support activities to improve the impact of their LPGs. The American Society for Microbiology (ASM), the Clinical and Laboratory Standards Institute (CLSI), and the College of American Pathologists (CAP), will each use at least two of their LPGs as models to better understand how to improve uptake and impact of these and future LPGs for their intended LPG users. In accordance with the funding opportunity announcement, the awarded organizations have selected model LPGs that concern laboratory testing for a disease or risk factor that has public health impact.

The CDC plans to submit separate packages to request OMB approval of new information collections for each of the three organizations that are involved in the overarching project: ASM, CLSI, and CAP. Separate submissions will be necessary for the overall project as each of the three organizations anticipate that their planning and activities timeline will differ. Moreover, it is anticipated that each of the three organizations will submit at least one additional request for OMB approval of a new information collection package at some time in the future. These future submissions will be asynchronous. This information collection request only concerns the CAP project.

Specifically, the CAP project will address two LPGs that are important to clinical testing and have a high public health impact: immunohistochemistry test validation (IHC) and an algorithm for diagnosing acute leukemia (ALA). The ALA LPG is being co-developed with the American Society of Hematology (ASH). These LPGs provide guidance on how to validate assays and accurately diagnose acute leukemia, respectively, based on a systematic review of published research and consensus-based judgment. It is expected that as a result of sustained improvements in the process of creating and updating these clinical LPGs, public health, which depends upon accurate and appropriate laboratory testing guided by the use of LPGs, will also generally benefit. The intended users of the CAP’s IHC LPG will include pathologists, clinical laboratory directors, and laboratory managers overseeing the IHC staining department. For CAP’s ALA LPG the intended users are pathologists and hematologists overseeing testing for acute leukemia.

This work involves demonstration projects that will show how the concepts in the Institute of Medicine report “Clinical Practice Guidelines We Can Trust,” which described how to improve dissemination and impact of LPGs by focusing on facilitators and impediments to LPG adoption, can be implemented through better metrics. The projects fit into CDC’s translational science agenda because the activities will contribute towards the U.S. Department of Health and Human Services’ Healthy People 2020 vision for “a society in which all people live long, healthy lives.” This work supports one of the Healthy People 2020’s missions to “improve practices that are driven by the best available evidence and knowledge” and several of the goals of Healthy People 2020 depend on accurate and reliable laboratory testing. It aligns with CDC’s Science Impact Framework to promote translation of science into practice through disseminating science, creating awareness, catalyzing action, effecting change, and shaping the future.

The CAP project is especially important to national cancer surveillance, which depends upon testing for accurate diagnosis and surveillance. The CAP LPGs that will be explored, IHC and ALA, aim to assure accuracy and reduce variation in immunohistochemical test results in all patient specimens and provide recommendations to help users accurately diagnose acute leukemia, respectively.

The CAP has already disseminated their IHC LPG *Principles of Analytic Validation of Immunohistochemical Assays* (<http://www.archivesofpathology.org/doi/pdf/10.5858/arpa.2013-0610-CP>) which was based upon their baseline survey. They are expected to complete and disseminate their ALA LPG *CAP/ASH Algorithm for Initial Work-Up of Acute Leukemia* in 2015. This cooperative agreement project will use surveys to collect information on users' awareness, perceptions, and understanding of these guidelines in order to improve patient testing, their health, and, as a result, public health as a whole. Users' adoption of the recommendations in these guidelines is critical as prior research has shown that some users are unaware of the requirements for analytic validation and accurately diagnosing acute leukemia. The surveys will allow the CAP to better understand which laboratories and individuals are unaware of their guidelines, some of the barriers to their uptake of its recommendations, and the gaps in understanding the proper ways to perform validation before IHC is placed in a clinical service and how to minimize diagnostic errors in acute leukemia.

Prior to entering into this cooperative agreement project with the CDC, the CAP had already completed a baseline IHC LPG information collection from laboratories that participated in the CAP's 2010 HER2-B (human epidermal growth factor receptor 2 for breast cancer) Immunohistochemistry Tissue Microarray Survey Program, including CAP-accredited and non-CAP-accredited laboratories. The survey found that written procedures were often not used for validating IHC assays, and there were perceived gaps in how validations were being conducted (Immunohistochemistry Validation Procedures and Practice: A CAP Survey of 727 Laboratories (Arch Pathol Lab Med 2013;137:19-25).

Subsequently, the CAP created and published an IHC LPG (<http://www.archivesofpathology.org/doi/pdf/10.5858/arpa.2013-0610-CP>). Because of this prior baseline assessment, for their cooperative agreement with the CDC, the CAP will only need to collect post-dissemination information. For their ALA LPG *CAP/ASH Algorithm for Initial Work-Up of Acute Leukemia*, the CAP will conduct a survey.

## **2. Purpose and Use of Information Collection**

There is a current lack of connection between the organizations that create and manage laboratory practice guidelines (LPGs) and the subsequent steps to ensure their eventual uptake and use. There are typically no metrics to evaluate changes in practices resulting from the LPG, nor are there ways to know what improvements would be warranted. Relevant data is undefined and unknown, with the exception of sales figures in some cases. Most LPGs are reviewed every few years to determine relevance and to assess whether they should be retired, updated, or entirely revised; these cycles provide regularly recurring opportunities to apply metrics. Unfortunately, useful data that could have been gathered is seldom collected. Targeted users are typically not asked whether they are aware of the LPG and, if they use it, how it might be improved. Data are also not collected on why they chose not to use the LPG or whether they modified it for uses. When it is time to review an LPG for revision or retirement, there is typically little information to inform the decision, other than the impressions of the guideline committee. In this context and given the stresses on the healthcare system caused by unnecessary and inappropriate testing, it is important for organizations that create and manage LPGs to better understand how to measure and increase impact of their LPGs.

The purpose for information collection is for the CAP to use the information about the two model LPGs, IHC and ALA, to identify gaps in their current approach for the creation, dissemination and uptake of their LPGs. Careful analysis of the information collected will allow the CAP to develop a comprehensive plan for improving future processes for LPG development and dissemination and allow them to demonstrate the value of using metrics to improve uptake and impact of their LPGs. With coauthors at CDC, collaborators at CAP will publish the results of this demonstration project to show other organizations that create LPGs that their impact can be enhanced by using metrics. Scientists at CDC will benefit from this work by improving our abilities to design and analyze survey questionnaires.

### **3. Use of Improved Information Technology and Burden Reduction**

The baseline survey for the ALA guideline will be disseminated on the Internet via the Survey Monkey software system. The CAP will email the link to take the online survey to 1045 pathologists and 55 hematologists that sign out cases who perform acute leukemia testing.

The method by which the CAP plans to disseminate the post-dissemination survey for the IHC guideline will differ from that for the ALA guideline. They disseminated the baseline IHC paper survey prior to this CAP-CDC cooperative agreement using the e-LAB Solutions modality. Because the CAP achieved an acceptable 70% response rate for the IHC baseline survey, they intend to employ the same method of dissemination for their post-IHC survey to target all laboratories who participated in the baseline survey. Moreover, they will not use an electronic means for collecting post-IHC information when they target non-CAP PT laboratories because those laboratories were identified using Centers for Medicare and Medicaid Services (CMS) Part B reimbursement requests and only physical, rather than e-mail addresses, are available to us.

### **4. Efforts to Identify Duplication and Use of Similar Information**

The CAP and CDC Project Officers are confident that this project does not duplicate other efforts or existing data collections.

The CDC Project Officers determined, following their review of the existing OMB-approved data collections located on the Office of Information and Regulatory Affairs, Office of Management and Budget website, that there are currently no surveys inquiring whether users of laboratory practice guidelines are aware of them and, if they use them, how they might be improved. In addition, they determined that there are no data on why these users chose not to adopt the recommendations or whether they made modifications before using them. There is little information available to inform guideline developers' decision on whether they should revise or retire guidelines. Furthermore, the CDC had consulted with numerous organizations that create LPGs, including ASM, CAP, and CLSI, and there was a consensus that they were not aware of all who actually use the laboratory guidelines, whether they are used in whole or part, and their perceptions of the guidelines.

### **5. Impact on Small Businesses or Other Small Entities**

According to the U.S. Small Business Administration website (<http://www.sba.gov/content/what-sbas-definition-small-business-concern>), a small business concern is “one that is independently owned and

operated, is organized for profit, and is not dominant in its field.” One example of a small business is one whose services’ receipts do not exceed \$2.5 million.

While some survey respondents may be employed in relatively small laboratories, it is not possible to estimate exactly how many responding laboratories would be considered small businesses, as defined by the U.S. Small Business Administration’s definition of a small business concern, because this information is not available to us. On the one hand, we would estimate that nearly all current CAP-accredited laboratories do not qualify as small businesses because they tend to be high-volume settings, and typically include hospital and reference laboratories. On the other hand, some of the 450 non-CAP-PT customers do tend to be smaller facilities. Assuming all laboratories that are recruited actually perform IHC testing, we estimate that 2668 will respond to the IHC survey (2885 CAP-PT customers + 450 non-CAP-PT customers) x 80%). Both populations represent laboratories that are CAP-accredited and non-CAP-accredited. If the response rate from these laboratories is approximately 80% as hoped, then there would be approximately 360 small businesses (450 non-CAP-PT customers x 80%) impacted, at maximum.

In order to reduce the burden for all respondents, including those working at smaller laboratories, a simple and accessible survey format will be used. The ALA survey will be accessible via the Internet, and an electronic link to the survey instrument will be provided so respondents can easily access the survey at their convenience, either at home or in the office. Both IHC and ALA surveys consist of questions which are short, written at a reading level appropriate to the target audience, and parsimonious. Respondents will not be asked to provide any extraneous information; rather, the survey questions strictly address their immunohistochemistry test validation and acute leukemia diagnostic practices.

## **6. Consequences of Collecting the Information Less Frequently**

The surveys for which we are requesting OMB approval will each be fielded only once under the project plan.

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

This request fully complies with the regulation of 5 CFR 1320.5.

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

A. As required by 5 CFR 1320.8(d), a notice of this proposed data collection appeared in the Federal Register, November 3, 2014, Vol. 79, No. 212, pp. 65219-65221 (Attachment B).

There were no public comments.

B. In 2014, the CDC Project Officers consulted with the following individuals to obtain their views on the ability to identify laboratories to survey using CMS reimbursement. We consulted Mr. Dettwyler, Ms. English, and Mr. McMurray concerning data elements to be recorded, disclosed, or reported, as they relate to Medicare Part B reimbursement data for the immunohistochemistry validation assay and IHC



and ALA survey instruments. We consulted survey design expert, Karen Wooten, to assure survey questions were carefully phrased and ordered.

The following provided consultation for identifying laboratories based upon their use of Current Procedural Terminology (CPT) codes for reimbursement requests:

William K. Dettwyler, M.T.

President of Codus Medicus Inc.

5555 Sunnyview Rd. NE

Salem, OR 97305

Phone: 503-399-9656, Fax: 503-588-5378, Cell: 503-871-5259

[William@CodusMedicus.com](mailto:William@CodusMedicus.com)

Roseanne English, BS

Analytic Data Management Lead, Division of Epidemiology, Analysis, and Library Services

Centers for Disease Control and Prevention

1600 Clifton Road NE

MS-E33

Atlanta, GA 30329

Phone: 404-498-2468, Fax: 404-498-1177, Blackberry: 404-368-1937

[rxel@cdc.gov](mailto:rxel@cdc.gov)

Paul McMurray

Statistician, Division of Epidemiology, Analysis and Library Services

Centers for Disease Control and Prevention

1600 Clifton Road NE

MS-E33

Atlanta, GA 30329

Phone: 404-498-6676, Fax: 404-498-1177, Mobile: 404-993-2293

[pzm5@cdc.gov](mailto:pzm5@cdc.gov)

The following provided consultation on survey design:

Karen Wooten, MA

Mathematical Statistician

Carter Consulting, Inc.

2310 Parklake Drive, NE, Suite 535

Atlanta, GA 30345

Phone: 770-939-2601

[kgw1@cdc.gov](mailto:kgw1@cdc.gov)

## **9. Explanation of Any Payment or Gift to Respondents**

No remuneration will be paid to respondents.

## **10. Assurance of Confidentiality Provided to Respondents**

The PRA Contact for this work, Division of Laboratory Programs, Standards, and Services Associate Director for Science, has reviewed this OMB application and has determined that the Privacy Act is not applicable. No patient health information is being collected. No contact information will be listed on any reports or summaries of findings. Neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents as the CAP will use the CAP Extract tool to remove identifiers. Moreover, for both the IHC post-dissemination and ALA baseline surveys, the CAP intends to review and report only aggregate results.

No individually identifiable information is being collected.

## **10.1 Privacy Impact Assessment Information**

### *Overview of the Data Collection System*

#### Immunohistochemistry Test Validation

The post survey for the IHC guideline includes questions about personal perspectives and preferences. The CAP will disseminate paper surveys (Attachment C) along with their PT mailings, to target laboratories enrolled in the CAP Proficiency Testing program, specifically, the HER2 (human epidermal growth factor receptor 2 for breast cancer), PIP (Performance Improvement Program in Surgical Pathology), and HQIP (HistoQIP Program for improving the preparation of histological slides) modules. One project goal is to better understand CAP-accredited laboratories' awareness, perceptions, understanding, and uptake of the IHC LPG. An additional goal is to explore the same issues with non-CAP-PT customer laboratories; for this cohort, the surveys will be sent via the US postal system, with a fax-back mechanism.

#### Acute Leukemia Algorithm

The baseline survey for the ALA guideline will be disseminated electronically via the Survey Monkey software system. (Attachment D) The link to the baseline survey for the ALA guideline will be disseminated via email. The CAP has an internal database of pathologists who have indicated specialization in hematopathology. The CAP will use a setting in Survey Monkey, their data collection software, to accept only one response per computer Internet Protocol (IP) address.

### *Description of the Information to be Collected*

The immunohistochemistry test validation post-guideline data collection (IHC) will complement the initial IHC survey with information on current laboratory practices regarding IHC.

The IHC post survey is designed to collect information on whether laboratories have a written procedure that outlines the steps needed for analytic validation of all new IHC assays, includes any specifications for validating IHC tests performed on various specimens, and whether their practices conform to the recommendations in *Principles of Analytic Validation of Immunohistochemical Assays*. It also queries their understanding of which changes are specified in the IHC LPG for non-FDA approved, non-predictive IHC assays and non-FDA approved, predictive marker IHC assays. Moreover, respondents to the survey are asked to answer questions with respect to all IHC assays in use in the laboratory at which they work.

In addition, the IHC survey is designed to collect information on individual perceptions of the IHC LPG. The survey includes questions on participant demographics, their awareness of the guideline, facilitators and barriers to their adoption of the recommendations into their laboratory practice, and how he or she plans to use the recommendations. Moreover, the survey contains questions on participant perceptions on some of the challenges when validating IHC assays.

The ALA survey includes questions about individual laboratory practices for diagnosing various types of acute leukemia and individual and laboratory reporting practices. The issues addressed will include: what kinds of clinical information are collected for new cases of acute leukemia, what kinds of specimens are tested and how frequently, what specific test methods are used, and other more specific technical data, including which specific mutations are tested.

During the information collection process, respondent information will be kept in a secure database. CAP staff responsible for analyzing the results or writing the final report will have an account to access the database of survey responses. The survey primarily asks for information regarding laboratorians' use of and opinions on laboratory testing practices and/or the use of algorithms for test selection to diagnose patients with leukemia. The survey will be completed through a web-based survey system, Survey Monkey. No CDC staff or contractors will have direct access to any information collected by the CAP. Importantly, the information collected will address voluntary practices that have no regulatory consequences. The information will be presented with findings in the aggregate, for example in peer-reviewed publications or presentations at scientific meetings. No personal or laboratory identifiers will be retained in the final survey dataset. The Privacy Act Checklist has also been included as (Attachment E).

No individually identifiable information will be collected.

1. The surveys for the IHC and ALA guidelines will inform participants that providing information is voluntary.
2. Because there will be no collection of information in identifiable form, consent will not be necessary.
3. Survey responses received by the CAP will be stored in a secure, password-protected database.
4. If the information is shared with CDC for additional analysis, the survey responses will be stored in a secure, password-protected database at the CDC and CAP facilities.

## **11. Justification of Sensitive Questions**

Information on criminal behavior, sexual behavior and attitudes, alcohol or drug use, religious beliefs, and race and ethnicity will not be collected.

## **12. Estimates of Annualized Burden Hours and Costs**

- A. The intended users of the CAP's IHC LPG and respondents to the IHC survey will include pathologists, clinical laboratory directors, and laboratory managers overseeing the IHC staining

department. The intended users of the CAP's ALA LPG and respondents to the ALA survey will include pathologists and hematologists overseeing testing for acute leukemia.

According to the CAP, the time it took participants to complete the IHC baseline survey, which was conducted prior to this CAP-CDC cooperative agreement, was 15 minutes. The IHC post-dissemination survey is expected to take 20 minutes to complete. The ALA baseline survey is expected to take an average of 25 minutes to complete.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Pathologists	IHC	834	1	20/60	278
	ALA	1045	1	25/60	435
Laboratory Directors	IHC	834	1	20/60	278
Laboratory Managers	IHC	1667	1	20/60	556
Hematologists	ALA	55	1	25/60	23
Total					1570

B.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
Pathologists	IHC	834	1	20/60	278	\$84.52	\$23496.56
	ALA	1045	1	25/60	435.42	\$84.52	\$36801.70
Laboratory Directors	IHC	834	1	20/60	278	\$51.23	\$14241.94
Laboratory Managers	IHC	1667	1	20/60	555.67	\$37.76	\$20982.10
Hematologists	ALA	55	1	25/60	22.92	\$84.52	\$1937.20
Total							\$97,460

\* The hourly wage rate for Pathologists and Hematologists, in the above table, was taken from the 2013 Bureau of Labor Statistics website. The hourly wage rate for Laboratory Directors and Laboratory Managers, in the above table, was taken from <http://www.mloonline.com/ebook/201403/resources/6.htm>. The hourly wage rate for laboratory directors and managers was calculated by taking the published salary on page 17 and dividing that by 2080 (working hours per year).

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

There are no capital and start-up costs nor operation and maintenance and purchase of services costs for this project.

#### 14. Annualized Cost to the Government

The total annualized cost to the Federal government is comprised of two CDC Project Officers collaborating with and providing advice to the College of American Pathologists project managers, as well as two CDC data experts within the Center. The cost for each CDC staff is estimated by multiplying the percentage time contributed toward this project, per individual, and their respective pay rates based on the GS pay scale for Atlanta (<http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2013/general-schedule/atl.pdf>). The U.S. Department of Health and Human Services Human Resources is awaiting Office of Personnel Management guidance for implementation of the GP scale in order to make it publically available.

One individual, a Medical Officer, with GP pay scale 15 step 4 (contributing 5% of their time), two individuals with GSA pay scales of Grade 14 (1 person contributing 10% and the other, 1% of their time) and one individual with GSA pay scale of Grade 13 (contributing 1% of their time) are included in the annualized cost to the Federal government.

Federal Employee	% Time Contributed to Project	Pay Rate
Senior Health Scientist	10%	\$131, 343
Medical Officer	5%	\$210, 704
Analytic Data Management Lead	1%	\$131, 343
Statistician	1%	\$111, 148
Total Annual Cost		\$26,094

#### 15. Explanation for Program Changes or Adjustments

This is a new data collection.

#### 16. Plans for Tabulation and Publication and Project Time Schedule

Activity	Time Schedule
Letters sent to respondents	1-3 months following OMB clearance
Data collection	4-6 months following OMB clearance
Validation and Analyses	7 months following OMB clearance
Publication	19-21 months following OMB clearance

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

There are no exceptions to the certification.

## **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.