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

Clinical and Laboratory Standards Institute

Request for Approval of New Data Collection

Supporting Statement A

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- Goal of study: To explore factors that may influence intended users of laboratory practice guidelines (LPGs) and find ways to improve the creation and utility of LPGs.
- Intended use of resulting data: The CLSI can define and use metrics to better inform the creation, revision, dissemination, promotion, uptake and use of their LPGs. The collected survey information will be analyzed to determine how *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities* (*POCT 12*) and *Glucose Monitoring in Settings without Laboratory Support* (*POCT 13*) LPGs should be created/disseminated and promoted to address barriers observed with specific sub-groups of health professionals.
- Data Collection Methods: A baseline survey (FGS1) will be administered (to all respondents listed in the burden table) during year 1 of the information collection and a post-implementation survey (FGS3) will be administered (to all respondents listed in the burden table) approximately 2.5 years thereafter. A second survey (FGS2) will be distributed 4-6 months after FGS1 distribution, but only to respondents who indicate on FGS1 that they are not familiar with either *POCT 12* or *POCT 13*, and who will, as a result, receive a free copy of the appropriate LPG prior to taking FGS2. All 3 surveys will be administered through the Epi Info7 software.
- Subpopulations to be studied: Point-of-care coordinators, laboratory directors, laboratory managers, laboratory supervisors, medical technologists, nurses, and medical doctors.
- Data Analysis: CDC Project Officers and CLSI Project Managers will analyze responses from the subpopulations that will be studied (stratified by size of hospital, type of physician office, or job title), and compare the FGS1, FGS2, and FGS3 responses between groups.

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- Clinical and Laboratory Standards Institute." CDC is requesting a three year approval to collect the information. This information collection falls under the Title 42 Public Health and Welfare Authorization Legislation included as Appendix A.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established minimum requirements for assuring the quality of 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: point-of-care coordinators, clinical laboratory directors, medical technologists, nurses, and medical doctors. 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 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 on 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 a new information collection 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 above-mentioned 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 data collection package at some time in the future. These future submissions will be asynchronous. This information collection request only concerns the CLSI project.

Specifically, the CLSI project will address two LPGs that are important to clinical testing and have a high public health impact: *POCT12, Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities* and *POCT13, Glucose Monitoring in Settings without Laboratory Support*. These LPGs provide guidance and recommendations for personnel monitoring patient glucose levels at sites that have access to a hospital laboratory and at locations, such as physician offices or nursing homes, which do not have an on-site moderate or high complexity laboratory. 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 CLSI's *POCT12* and *POCT13* LPGs will include point-of-care coordinators, clinical laboratory directors, managers, supervisors, medical technologists, nurses, and medical doctors.

This work involves demonstration projects that will show that 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 of 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 CLSI project is especially important to diabetes surveillance and limiting morbidities, such as cardiovascular disease, amputations and blindness, which depend upon accurate glucose monitoring for glycemic control. The CLSI LPGs that will be explored, *POCT12* and *POCT13*, aim to assure accuracy and reduce variation in point-of-care fingerstick glucose tests that are performed in sites with and without access to a hospital laboratory, respectively.

This cooperative agreement project will use a survey, “Fingerstick Glucose Survey” (FGS), to collect information on users’ awareness, perceptions, and understanding of the 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 accurate use of the point-of-care glucometer, including the need to decontaminate the meter to prevent transmission of hepatitis viruses. The survey will allow the CLSI 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 point-of-care fingerstick glucose tests.

The CLSI plans to collect information using the same survey instrument on three separate occasions. During the first information collection (FGS1), all targeted respondents, which include point-of-care coordinators, laboratory directors, laboratory managers, laboratory supervisors, medical technologists, nurses, and medical doctors, will be asked to complete the survey. Respondents who indicate that they are not familiar with either *POCT12* or *POCT13* will be asked to provide an email address and offered a free copy of the applicable LPG. This subset of respondents will be asked to complete the same survey 4-6 months after receiving the free LPG (FGS2). After analysis of the information collected during the first 2 surveys, CLSI will make improvements to *POCT12* and *POCT13*, such as provision of educational materials or helpful products such as quality control logs, and may also alter their marketing campaigns to address issues related to awareness and use of CLSI documents. The third survey (FGS3) will be sent to all targeted respondents approximately 2.5 years after the first survey and will be used to assess how the modifications to the CLSI procedures prompted by the results of the first 2 surveys have impacted the audiences of *POCT12* and *POCT13*. Respondents that received a free copy of *POCT12* or *POCT13* following the first survey will also be contacted by email and asked to take the third survey.

2. Purpose and Use of Information Collection

There is a current lack of connection between the organizations that create and manage LPGs and the subsequent steps to ensure 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 may 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 it 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 this information collection is for the CLSI to use the information about the two model LPGs, *POCT12* and *POCT13*, 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 CLSI 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 of their LPGs. With coauthors at the CDC, collaborators at the CLSI 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 and to make CDC guidelines more effective.

3. Use of Improved Information Technology and Burden Reduction

The CLSI survey will be disseminated to the respondents on the Internet using Epi Info 7. The CLSI will distribute the link to the survey by both email and on a postcard, depending upon what contact information is available for the laboratory. Use of an electronic survey format will reduce burden on the respondents because they can access and complete the survey on the internet and will not be required to mail back the response. Use of Epi Info 7 allows development of automated skip patterns that guide respondents to the next appropriate question based on their responses, which makes it easier for respondents to navigate the survey.

4. Efforts to Identify Duplication and Use of Similar Information

The CLSI 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 that are located in 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 its recommendations or whether they made modifications before using them. There is little information available to inform guideline developers' decision on whether to revise or retire guidelines. Furthermore, the CDC had consulted with numerous organizations that create laboratory practice guidelines, 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 small physician office 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. We would estimate that nearly all hospital based laboratories do not qualify as small businesses because they tend to be high-volume settings, and physician office laboratories tend to be smaller facilities. We expect that approximately 24,000 (29,627 targeted laboratories invited to participate in Year 1 x 80%) individuals will take the survey during Year 1 and Year 3 of the information collection. We expect that approximately 15,000 physician office laboratories which will receive the POCT13 survey during Years 1 and 3, and approximately 7,500 physician office laboratories (i.e., 50% of the total physician office laboratories, which are estimated to not have prior familiarity with POCT13) will receive the POCT13 survey during year 2.

In order to reduce respondent burden for all respondents, including those working in physician office laboratories, a simple and accessible survey format will be used. The 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. The survey consists of 29 questions which are short, written at a reading level appropriate to the target audience, and parsimonious. Because skip patterns will be used throughout the survey, respondents will only need to answer a maximum of 23 questions. Respondents will not be asked to provide any extraneous information; rather, the survey questions strictly address their familiarity with CLSI and either *POCT12* or *POCT13*. The survey also has questions related to the implementation of the LPG recommendations and some demographic questions. All of the questions can be answered by selecting amongst provided answer choices, and none of the answers requires any input of free text.

6. Consequences of Collecting the Information Less Frequently

The survey for which we are requesting OMB approval will be fielded three times under the project plan. This is necessary to measure the respondents' awareness and opinions of the CLSI and the LPG documents as well as their response to improvements, such as addition of educational supplements to enhance the usefulness and value of *POCT12* and *POCT13* and improved marketing to increase awareness based on findings from the first and second surveys.

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, December 11, 2014, Vol. 79, No. 238, pp. 73588-73589 (Appendix B).

There were no public comments.

B. No additional individuals, besides CDC Project Officers and CLSI staff were consulted.

9. Explanation of Any Payment or Gift to Respondents

No monetary remuneration will be paid to respondents. Respondents that have not read *POCT12* or *POCT13* will be offered a free copy of one document as a gift for completing the survey. These individuals will be informed that the CLSI will contact them again in 4-6 months and 2.5 years, using the email address that they provide, and that they will be asked to complete the survey. Respondents that already have a copy of *POCT12* or *POCT13* at the time they take the first survey will be offered a free copy of any other CLSI point-of-care LPG.

10. Assurance of Confidentiality Provided to Respondents

The PRA Contact for this work, Division of Laboratory Systems 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. CDC will not analyze data in an individually identifiable form.

10.1 Privacy Impact Assessment Information

Overview of the Data Collection System

First and Third Surveys

The survey data will be collected using Epi Info 7. The CLSI will solicit participation from physician office laboratories, Department of Defense laboratories, and hospitals that offer point-of-care glucose testing. A link to the survey (Appendix C & Appendix D) will be distributed to all targeted respondents either by email (Appendix E & F) or postcard (Appendix G-I & Appendix J-L). Participants will be recruited by the Commission on Office Laboratory Accreditation (COLA), the Joint Commission and a Point-of-Care Coordinator network, who have all agreed to distribute the link to the survey in an email message through their membership mailing lists. Participants will also be solicited by email or postcard through mailing lists purchased by CLSI from Clinscan and the American Hospital Association, respectively. Clinical sites offering point-of-care glucose testing in the Department of Defense medical system will also be asked via email to participate through the Department of Defense Clinical Laboratory Improvement Program (CLIP). In order to obtain the needed number of respondents for a statistically valid study, additional laboratories, selected at random from a database of Clinical Laboratory Improvement Amendment (CLIA) certificate holders, the Online Survey Certification and Reporting System (OSCAR), will also be solicited by postcard. The survey will contain instructions to direct it to the individual in each laboratory responsible for the development and revision of procedures for fingerstick glucose testing. Directing the survey to the individual with this specific responsibility will help to ensure that only one response will be obtained for each participating laboratory. Respondents include point-of-care coordinators, clinical laboratory directors, managers, supervisors, medical technologists, nurses, and medical doctors.

Second Survey

The second survey (Appendix D) will be distributed approximately 4-6 months after the initial survey (Appendix C) and will only target respondents from the first survey who indicated that they were not familiar with *POCT12* or *POCT13*, and therefore, will have received a complimentary copy of the appropriate LPG. This survey will be the same as the first survey, but the respondents will be able to answer additional questions after they have reviewed the LPG. A link to the survey will be distributed by email to these respondents who provided the email addresses during the first survey. Respondents that received a free copy of *POCT12* or *POCT13* following the first survey will also be contacted by email and asked to take the third survey (Appendix D).

Description of the Information to be Collected

The CLSI survey is designed to collect information on participant demographics, awareness of the CLSI, awareness of *POCT12* and *POCT13*, use of *POCT12* and *POCT13* in their laboratories, facilitators and barriers to their adoption of the recommendations into their laboratory practice, and questions about perceived value of the documents.

During the information collection process, respondent information will be kept in a secure, password-protected database. The survey primarily asks for information regarding participants' awareness and use of and opinions about the two CLSI LPGs. The survey will be completed through a web-based survey system: Epi Info7. The only identifying information collected will be email addresses from a subset of the respondents, specifically those who indicate on the first survey that they were not familiar with *POCT12* or *POCT13*. The CLSI will request respondents to provide an email address so that they may send respondents who indicated they were not familiar with either of the CLSI LPGs, a link to select a single complimentary electronic copy of a CLSI guideline related to fingerstick glucose testing. The email addresses will not be linked with data from the surveys nor stored in a CDC database. No CDC staff or contractors will have direct access to any data collected by the CLSI. 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 Appendix M.

1. The CLSI survey will inform participants that providing information is voluntary.

2. Survey responses received by the CLSI will be stored in a secure, password-protected database.

3. If the data are shared with CDC for additional analysis, the survey responses will be stored in a secure, password-protected database at the CDC facility.

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 CLSI's survey will include point-of-care coordinators, clinical laboratory directors, managers, supervisors, medical technologists, nurses, and medical doctors.

Based on a pilot study on 9 participants, the CLSI estimated that it will take approximately 15 minutes to complete the survey. Respondents that have not read *POCT12* or *POCT13* may require less time as they will be responding to fewer questions.

The annualized burden is 6173 hours. This is calculated by dividing the total burden hours by the number of years (three) over which data is collected. The maximum burden is 7407 hours that occurs in year 1 and year 3.

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Point-of-Care Coordinators	FGS1	500	1	15/60	125
	FGS2	250	1	15/60	63
	FGS3	500	1	15/60	125
Laboratory Directors	FGS1	4276	1	15/60	1069
	FGS2	2138	1	15/60	535
	FGS3	4276	1	15/60	1069
Laboratory Managers	FGS1	4276	1	15/60	1069
	FGS2	2138	1	15/60	535
	FGS3	4276	1	15/60	1069
Laboratory Supervisors	FGS1	4276	1	15/60	1069
	FGS2	2138	1	15/60	535
	FGS3	4276	1	15/60	1069
Medical Technologists	FGS1	7800	1	15/60	1950
	FGS2	3900	1	15/60	975
	FGS3	7800	1	15/60	1950
Nurses	FGS1	5000	1	15/60	1250
	FGS2	2500	1	15/60	625
	FGS3	5000	1	15/60	1250
Medical Doctors	FGS1	3500	1	15/60	875
	FGS2	1750	1	15/60	438
	FGS3	3500	1	15/60	875
Total					18520

B. The annualized burden cost is $347,550. This is calculated by dividing the total cost by the number of years (three) over which data is collected.

Type of Respondent	Form	Number of	Number of	Average Burden	Total	Hourly Wage	Total Responden

	Name	Respondents	Responses per Respondent	per Response (in hours)	Burden Hours	Rate*	t Costs
Point-of-Care Coordinators	FGS 1	500	1	15/60	125	$33.13	$4141.25
	FGS 2	250	1	15/60	63	$33.13	$2087.19
	FGS 3	500	1	15/60	125	$33.13	$4141.25
Laboratory Directors	FGS 1	4276	1	15/60	1069	$48.72	$156245.04
	FGS 2	2138	1	15/60	535	$48.72	$78098.16
	FGS 3	4276	1	15/60	1069	$48.72	$156245.04
Laboratory Managers	FGS 1	4276	1	15/60	1069	$37.76	$40365.44
	FGS 2	2138	1	15/60	535	$37.76	$20201.60
	FGS 3	4276	1	15/60	1069	$37.76	$40365.44
Laboratory Supervisors	FGS 1	4276	1	15/60	1069	$37.76	$40365.44
	FGS 2	2138	1	15/60	535	$37.76	$20201.60
	FGS 3	4276	1	15/60	1069	$37.76	$40365.44
Medical Technologists	FGS 1	7800	1	15/60	1950	$28.59	$55750.50
	FGS 2	3900	1	15/60	975	$28.59	$27875.25
	FGS 3	7800	1	15/60	1950	$28.59	$55750.50
Nurses	FGS 1	5000	1	15/60	1250	$33.13	$41412.50
	FGS 2	2500	1	15/60	625	$33.13	$20706.25
	FGS 3	5000	1	15/60	1250	$33.13	$41412.50
Medical Doctors	FGS 1	3500	1	15/60	875	$90.00	$78750.00
	FGS 2	1750	1	15/60	438	$90.00	$39420.00
	FGS 3	3500	1	15/60	875	$90.00	$78750.00
Total							

$1,042,650.00

* The hourly wage rate for all respondent types, with the exception of Laboratory Managers and Laboratory Supervisors, in the above table was taken from the 2013 Bureau of Labor Statistics website. The hourly wage rate for Laboratory Managers and Laboratory Supervisors, in the above table, was taken from http://www.mloonline.com/ebook/201403/resources/6.htm. The hourly wage rate for laboratory managers and supervisors was calculated by taking the published salary on page 17 and dividing that by 2080 (working hours per year).

The number of respondents indicated in the burden tables above was derived by estimating the number of participants from each contact list likely to find *POCT 12* or *13* of value (see table below). We estimated the number of participants by job title from each contact list (e.g., Clinscan, COLA, Department Of Defense, etc. – See Supporting Statement B, section 1). We further stratified participants to setting; physician office laboratory (POL) versus hospitals/clinics (HCs). *POCT 12* is most relevant to hospital and clinical settings whereas *POCT 13* is most relevant to physician office laboratories.

Estimated distribution of potential respondents across respondent categories in the burden tables is provided below.

	Number of Respondents in Burden Table (see Supporting Statement A)	Clinscan	COLA		Department of Defense		Point-of-Care Coordinators		Joint Commission	American Hospital Association	OSCAR	
		HC	POL	HC	POL	HC	POL	HC	HC	HC	POL	HC
POCT Coordinators	500						250	250				
Laboratory Directors	4276	1676	1000	500					200	500	400	
Laboratory Managers	4276	1676	1000	500					200	500	400	
Laboratory Supervisors	4276	1676	1000	500					200	500	400	
Medical Technologists	7800			1000	1000	1000			1000	1000	800	2000
Nurses	5000		1000								4000	
Medical Doctors	3500		1000							500	2000	
Total	29628	5028	5000	2500	1000	1000	250	250	1600	3000	8000	2000

Legend:
HC= hospitals/clinics
POL= physician office laboratory

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 Clinical and Laboratory Standards Institute project managers and one CDC data expert 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).

Three individuals with GSA pay scales of Grade 14 (3 people contributing 20%, 10%, and 5% of their time) are included in the annualized cost to the Federal government.

Federal Employee	% Time Contributed to Project	Pay Rate
Health Scientist	20	$117, 873
Geneticist	10	$131, 343
Statistician	5	$131, 343
Total Annual Cost		$43,276.00

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

Activity	**Time Schedule**
Letters sent to respondents	1 - 2 months after OMB approval
Data collection, first survey	3 - 5 months after OMB approval
Data collection, second survey	7 – 10 months after OMB approval
Validation and analysis	11 - 16 months after OMB approval
Modify and distribute LPGs	17 - 31months after OMB approval
Data collection, third survey	31 - 36 months after OMB approval
Validation and analysis	37 - 39 months after OMB approval
Publication	43 months after OMB approval

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.