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

College of American Pathologists

OMB #0920-1067 (Expiration 05/31/16)

Request for Approval of Revised Data Collections

Supporting Statement A

April 20, 2016

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- Goal of study: As a follow up to their completed IHC post-survey (under OMB #0920-1067) the CAP is now interested to learn more about the issues that underlay the survey findings. Additional qualitative analyses using telephone interviews will help CAP to identify the barriers such as lack of awareness, familiarity, and agreement with the guideline recommendations. In addition, the CAP wishes to use focus groups to explore in depth the facilitators such as clarity, toolkits and educational offerings which may have enabled laboratories to adopt their recommendations.
- Intended use of resulting data: The collected qualitative data will be analyzed to determine how the IHC LPG should be promoted to address barriers and facilitators observed with specific sub-groups of health professionals.
- Methods to be used to collect: Telephone interviews and two in-person focus groups will be conducted of the IHC LPG post survey respondents using questions revised from the previous survey questionnaire to allow a fuller exploration of the factors that underlie the adoption or non-adoption reasons and rates by laboratorians. .
- Subpopulations to be studied in this revision: Pathologists and various laboratory professionals.
- How data will be analyzed: The responses captured verbally and in person will be analyzed qualitatively, therefore no specific biostatistical tests are planned. The individual responses will be aggregated and analyzed to address the various reasons why laboratories adopt (or do not adopt) all or some of the IHC LPG recommendations.

** This ICR requests to use qualitative methods to follow up on the results of the IHC post survey, which has been completed under OMB 0920-1067 and indicates in preliminary data analyses the need to further explore the impediments and facilitators that affect uptake and use of the guideline. The questions to be used in the proposed telephone interviews and focus groups are a revision to the previously approved survey instrument but will incur reduced burden. **

1. Circumstances Making the Collection of Information Necessary

Background

This is a revision request for an OMB approved information collection, "Improving the Impact of Laboratory Practice Guidelines (LPGs): A New Paradigm for Metrics- College of American Pathologists." CDC is requesting a revision of the approved data collection under OMB #0920-1067, exp. 5/31/2016. The revised data collection will involve using telephone interviews and focus groups as a follow-up to the completed survey. A one year approval to collect the information as one part of this five-year cooperative agreement is requested. This information collection falls under the Title 42 Public Health and Welfare Authorization Legislation included as **Attachment A**.

CDC funded the College of American Pathologists (CAP) as one of three professional organizations in the 5-year cooperative agreement projects collectively entitled "Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics" in 2013. The CAP project described below, which was approved under OMB #0920-1067, is the basis for additional information collection, for which we are requesting a revision. The CAP has been addressing 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). 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 sustained improvements in the process of creating and updating these clinical LPGs will guide CAP and the laboratories to contribute accurate and appropriate laboratory testing to public health. As of the end of 2015, a baseline ALA survey and an IHC post-survey were completed under OMB #0920-1067. The CAP is analyzing results from their IHC post-survey and they wish to follow up to explore key findings relating to awareness and adoption of the IHC LPG.

This revision request only concerns the IHC LPG. We are requesting a revision to the OMB-approved 0920-1067 package by adding information collections using telephone interviews and focus groups as a follow-up to the completed IHC LPG post-survey. The questions to be used for the telephone interviews and focus groups are based on the questions and results of the IHC post survey, to help CAP and CDC better understand the impediments and facilitators that affect uptake of the IHC LPG. The intended participants in the proposed telephone interviews and focus groups will be selected from the IHC post survey respondents which include pathologists, pathology chairs, clinical laboratory directors, laboratory managers overseeing the IHC staining department, laboratory supervisors, and histotechnologists.

This revision request represents a decrease in new burden compared to the completed surveys under the existing OMB #0920-1067. This revision request seeks approval to add two new collections that are based upon findings from the IHC post-survey: (1) a telephone interview of laboratory professionals who perform IHC testing, and (2) focus groups of laboratory professionals who perform IHC testing.

2. Purpose and Use of Information Collection

The revision requested will help the CAP better understand how to address impediments to uptake and use of their LPGs. There are typically no data collected on why laboratory professionals chose not to use a CAP LPG or whether they modified it for uses. The additional data that will be collected by CAP will

allow them to better understand the impediments and how laboratory professionals want to be educated about LPGs.

Careful analysis of the information collected for the entire project 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. We propose to conduct telephone interviews that will explore the impediments and facilitators that affect uptake and use of the CAP IHC LPG. This will be followed by two focus groups, arranged by peer group of pathologists (pathologists, pathology chairs, and laboratory directors) and non-pathologists (laboratory managers, laboratory supervisors and histotechnologists), which will allow us to collect information on the current usage of CAP's tools and resources (toolkit) to facilitate implementation of the IHC guideline for its future improvement. The questions we are submitting for this ICR will allow a sub-set of respondents to describe what they believe are facilitators and impediments to IHC LPG use.

A series of open-ended questions based on the IHC post-survey results will be used as a script to conduct telephone interviews. CAP will randomly sample participants who completed the IHC post survey. These open-ended questions are designed to examine the knowledge, attitude and behavior barriers regarding adoption and uptake of clinical practice guidelines, specifically the *Principles of Analytic Validation of Immunohistochemical Assays* published by CAP in 2014. The script will include an introduction to the CDC-CAP cooperative agreement and explain the goal of the project (Attachment C and Attachments Ci and Cii supplemental information). The introduction will include the details of the voluntary nature of the interview, the time expected to complete the interview, which is approximately 20 minutes, and that the individual-specific responses are anonymous and will not be shared with CDC or in any report or publication. The script is intended to be a framework only as some participants' responses may lead to another question; hence, examples of probe questions are provided. The telephone interview is not intended to capture quantitative data duplicative of the IHC post-survey. Mr. Ronald Brooks from Strategic Business Innovations (SBI), the CAP's experienced contractor, will be conducting the telephone interviews and have access to each laboratory respondent's original 2015 survey data as well as the aggregate data. The respondents' original survey responses are intended for reference only and are not meant to interrogate the participant as the telephone interview will be conducted approximately 6-12 months past the post-survey and personnel and procedures may have changed in that timeframe. The telephone interview script **(Attachment C1)** is designed to collect opinions and perceptions of the laboratory professionals on the usefulness and/or difficulty in implementing the IHC LPG. The 40 interviewees may include some individuals who are unaware of or not familiar with the guideline (Topic 1 of the Script), Strategic Business Innovations will capture that information and end the conversation. That information will not be counted as part of the 40 completed interviews but will be documented as a partial interview with the potential knowledge gained for CAP to improve dissemination (Refer to Section 10 of this document for further description). If the interviewee is familiar with and aware of the guideline, Strategic Business Innovations will actively listen and manually write out the answers and conversations. No audio or video recordings will be performed. The manual results will be transcribed to Word and Excel documents accordingly and an Excel spreadsheet will be created to support thematic analysis. CDC will receive an aggregate summary of the interviews with no specific individual information. Strategic Business Innovations will have a list of 121 CAP PT and non-CAP PT laboratory professionals who completed the IHC post-survey in 2015 with the individual's title or position and phone number and ask to speak to that person **(Attachment C)**. For our estimates of burden and based on CAP's experience, we assume that only one out of every three laboratory professionals called will result in a completed interview. The 121 laboratory professionals will include a random sampling representing CAP PT laboratories and will include all of the non-CAP

PT (laboratories identified by Centers for Medicare & Medicaid Services billing codes that do not enroll in CAP PT products) respondents to the IHC survey. Strategic Business Innovations will call the laboratory professionals on the list until 40 have fully participated in the telephone interview questions. For our estimates of burden and based on CAP's experience this will include 20 pathologists, 10 laboratory directors, and 10 laboratory managers. Strategic Business Innovations will capture specific reasons for those individuals who did not wish to participate in the telephone interview along with those who request additional follow-up from CAP staff. Since this is not a longitudinal study, respondents will not be re-contacted in the future.

Based upon results from the telephone interviews, CAP will follow up with a series of open-ended questions **(Attachment D)** to further explore the usage of CAP tools and resources (toolkit) that may help facilitate adoption of the IHC LPG and improve the LPG and toolkit for future revisions. The CAP designed an invitation letter **(Attachment E)** to recruit individual pathologists (e.g., pathologists, pathology chairs, laboratory directors) and non-pathologist laboratory professionals (e.g., laboratory managers, laboratory supervisors, histotechnologists) who are registered to attend the American Society for Clinical Pathology (ASCP) meeting in Las Vegas, Nevada on September 14, 2016 to invite them to participate in a focus group session. The focus groups will be organized by peer groups (pathologists and non-pathologist laboratory professionals as described above) and will endeavor to examine the knowledge, attitude, and behavior barriers and facilitators to adoption and uptake of laboratory practice guidelines, specifically the *Principles of Analytic Validation of Immunohistochemical Assays* published by CAP in 2014. By convening the focus groups at the ASCP meeting, CAP will be able to recruit from a large population of laboratory professionals who are representative of the respondents from the IHC post-survey. The 121 laboratory professionals contacted to participate in the telephone interview will not be included in the pool of focus group participants. Once CAP has contacted 40 individuals who meet the requirements across three professional categories (pathologists, laboratory directors and laboratory managers), they will terminate the telephone interviews.

The CAP will attempt to obtain the list of ASCP registrants and cross-reference laboratory professionals from both the non-CAP PT customer laboratories and the CAP PT customers who returned the post-survey in 2015 via a random sampling based on profession/job title to request their participation. The invitation **(Attachment E)** will be sent via both email (if provided) and paper U.S. mail to 200 individuals, with the options to respond electronically by fax, email scan, or via paper U.S. mail. It is anticipated that invitation recipients will take no longer than 5 minutes each to read and respond to the invitation. The CAP will attempt to recruit 4 pathologists, 4 pathology chairs, and 4 laboratory directors for one focus group; and for the second focus group, 4 laboratory managers, 4 laboratory supervisors, and 4 histotechnologists. Based upon the responses to CAP's invitation (at the bottom of Attachment E), the CAP will select the respondents by profession/job title first and then attempt to fill each of the focus group sessions with an approximately equal representation of pathologist and non-pathologist laboratory professional respondent types on a "first come" basis." The CAP will then confirm that each focus group attendee will plan to participate in the focus group. The invitation to participate in-person will include an introduction to the CDC-CAP cooperative agreement and explain the goal of the project **(Attachment E)**. The invitation will include the details of the focus group: voluntary participation; no compensation (other than a light meal); lasting no more than 60 minutes and no individual or laboratory participant information will be identified in any publications or shared with the CAP or the CDC other than the cooperative agreement project members present in the room. Among the 200 individuals contacted, only the 24 who are selected to participate in a focus group session will each be asked to read and submit a signed consent form **(Attachment F)** prior to the session (which is included in the 60 minute burden time to complete a focus group session).

The CAP's experienced contractor, Strategic Business Innovations, will moderate the focus group discussions. For our estimates of burden and based on CAP's experience each of the 2 in-person sessions will include up to 12 individuals and be divided into peer groups of pathologists and non-pathologist laboratory professionals (laboratory managers, laboratory supervisors, and histotechnologists) responsible for IHC testing. The room will be arranged in a U-shape or board-room style with capacity for 12 participants, 1 contracted moderator, 2 CAP staff, 1 CDC staff, and 1 CAP guideline author. As the optimal number of focus group participants is approximately 8-12 individuals, CAP will invite and confirm up to 12 individuals for each of the focus group sessions. No minimum number will be required to hold the focus group as CAP believes valuable information could still be collected. CAP will provide blank name tags and the following handouts: a summary of recommendations **(Attachment G, pgs. 1-2)**, the guideline manuscript **(Attachment G, pgs. 3-14),** the methodology supplement (Attachment G, pgs. 15-55), a pdf of the PowerPoint teaching presentation (Attachment G, pgs. 56-70), the frequently asked questions document **(Attachment G, pgs. 71-74)** and a review article **(Attachment G, pgs. 75-78)**.

3. Use of Improved Information Technology and Burden Reduction

The telephone interview and focus group questions for this revision request will not be disseminated with improved information technology.

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.

Some of the OMB cleared IHC post-survey questions (completed information collection under OMB #0920-1067) will be used to frame the telephone interview questions and focus group questions and probes for the revision request; this will facilitate the reduction of burden for the respondents involved in the qualitative portion of the project. Since the pool of participants for the information collections to be submitted with this revision request will come from the IHC post-survey responders, CAP and CDC estimate that approximately 18 small businesses will be impacted.

6. Consequences of Collecting the Information Less Frequently

The qualitative instruments included in this described in this revision request will each be fielded only once under the project plan. Our analysis of the IHC post-survey results demonstrated that we need to collect additional qualitative information, first with telephone interviews and finally in structured focus groups, to fully understand the impediments and opportunities to improve uptake of the IHC LPG. Not collection this information will prevent us from understanding how to interpret and use results from the IHC post-survey.

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 24, 2015, Vol. 80, No. 226, PP. 73188-73190 **(Attachment B)**.

There were no public comments.

B. In 2015, the CAP contracted Strategic Business Innovations who is working with their Senior Biostatistician and Center Director to design and conduct the telephone interviews and in-person focus groups, upon OMB approval of this revision request.

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9. Explanation of Any Payment or Gift to Respondents

No remuneration will be paid to telephone interview or focus group respondents. Moreover, the CAP will not be offering any incentives to telephone interview participants. However, as a token of appreciation, the CAP will offer a light meal to participate in one of the two 60-minute focus group sessions. Meals will include a morning breakfast and afternoon lunch. The total value is estimated to be

no more than $50.00 per person for the breakfast and $60.00 per person for lunch. The participants will have already travelled to the ASCP annual professional meeting that is being held at the same city in Nevada. Because the participants will be busy attending the conference, these focus groups must be held at meal times. Based on CAP's experience with focus groups in the past, providing a light meal is considered to be the standard practice. CDC does not consider the provision of meals to be coercive.

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

The CDC Center for Surveillance, Epidemiology, and Laboratory Services Information Systems Security Officer has reviewed this request and has determined that the Privacy Act does not apply because the information collected will not be stored or maintained in identifiable form in any CDC information system nor will any data be retrievable by any personally identifiable elements.

Procedures to be taken to protect confidentiality and ensure data security include the following. No patient health information will be collected during the telephone interviews and the focus groups, nor will any respondent's contact information be listed on any reports or summaries of findings. The CAP owns all information collected from the telephone interviews and focus groups and will not share any identifiable information with anyone external to the organization. CAP will have multiple in-place controls to safeguard the information collected prevent unauthorized access or use. Physical controls include access limit to the area of the CAP Pathology and Laboratory Quality Center which conducts this project. Technical controls include user identification and password controls permitting only the Sr. Biostatistician to access the laboratory information collected from the IHC post survey, the CAP contractor, to access the contact information of the 121 IHC survey respondents who indicated their job title only will be contacted for the telephone interviews, and the Sr. Biostatistician, Center Director along with CAP contractor to access the identities of the individuals who participated in the completion of the telephone interviews or the focus groups. However, the CAP intends to review and report only aggregate results for both. In addition, the telephone interview responses will only be captured categorically as one of the following four outcomes: partial interview, complete interview, decline interview and never called. This information will then be provided back to CAP staff without any individual or laboratory identifiers on the final list. The information collected will only be active for duration of the CAP-CDC cooperative agreement (until August 2018).

For information collected under existing OMB# 0920-1067 and this revision request, respondent information has been and will continue to be kept in a secure, password-protected database with physical, technical, and administrative controls. Specifically, CAP uses the following physical controls: guards/security officers, identification badges, key cards, closed circuit TV. For technical controls they use: user identification, passwords, firewall, virtual private network (VPN), encryption, intrusion detection system (IDS), and public key infrastructure (PKI). Administrative controls include: a plan to backup the data, stored onsite or offsite, very limited, need-to-know access to the data so no comprehensive training plan is needed, and requirements for the contractor, Mr. Brooks, to ensure adherence to privacy provisions and practices.

CAP staff responsible for analyzing the results or writing the final report will have an account to access the database of survey responses. No CDC staff or contractors will have direct access to any information collected by the CAP. Importantly, the information that has been collected and will be collected if OMB approves the revision, 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.

Although CAP's contractor will have access to the identities of the individuals who participate in the completion of the telephone interview and Sr. Biostatistician and Center Director will have access to the focus group participants along with CAP contractor, information collected will not be presented to CAP or CDC in identifiable form. Telephone interview and focus group participants will be informed that their responses are anonymous and will not be shared with CDC. In addition, focus group participants will be provided with a consent form before the session begins. **(Attachment F).**

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

IRB Approval

The Acting Associate Director for Science, Division of Laboratory Systems, determined that the information collection is not research involving human subjects; IRB approval is not required. **(Attachment H)**

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.

In keeping with the overall purpose of this cooperative agreement project, we are requesting approval of this revision request to collect additional information via telephone interviews and focus groups regarding the implementation of the IHC LPG. The pool of participants for the telephone interviews will come from the respondents who completed the IHC post-survey, specifically pathologists, laboratory directors, and laboratory managers. . The pool of participants for the focus groups will come from the respondents who completed the IHC post-survey and also include pathology chairs, laboratory supervisors, and histotechnologists. For this request, the CAP will collect information via 40 telephone interviews (20 pathologists, 10 laboratory directors, and 10 laboratory managers). The telephone interview questions **(Attachment C1)** are scripted to be completed within 20 minutes by each respondent. (0.33 hour per respondent or ~13 hours total). Because the CAP anticipates that approximately 121 laboratory individuals (41 pathologists, 40 laboratory directors, and 40 laboratory managers) will need to be contacted **(Attachment C)** to reach 40 individuals who will voluntarily participate, and the burden for those individuals who will not go on to participate (81) in the telephone interview is one minute, the total burden for individuals who decline participation is 81 minutes (1.35 hours).

In addition, the CAP would like to conduct 2 focus group sessions **(Attachment D)** and invite 12 participants **(Attachment E)** to each of the sessions, composed of the following respondent types: (4) pathologists, (4) pathology chairs, (4) laboratory directors, (4) laboratory managers, (4) laboratory supervisors, and (4) histotechnologists). Each of the focus groups will last no more

than 60 minutes (1.0 hours) which is based on standard focus group planning instructions, inclusive of time required to complete informed consent **(Attachment F)** (24 hours or 1,440 minutes total burden). It is anticipated that 200 individuals, will be contacted to determine their availability to participate in one of two focus group sessions and each will take no longer than 5 minutes to read and respond to the invitation letter (~17 hours). The 200 individuals contacted will be composed of the following respondent types: (34) pathologists, (33) pathology chairs, (33) laboratory directors, (34) laboratory managers, (33) laboratory supervisors, and (33) histotechnologists.

This revision includes three types of laboratory professionals who were not included in the original OMB-approved submission: pathology chairs, laboratory supervisors, and histotechnologists. Because the OMB-approved IHC post-survey has been completed, this request for OMB approval of additional data collection (telephone interviews and focus groups) is a reduction of burden. Including both telephone interviews and focus groups, the total new burden for this revision request will be ~56 hours which is a reduction of 1,512 hours from the previously approved submission. A total of 321 respondents (121 invited to take the telephone interview and 200 invited to participate in focus groups), is a reduction of 4,114 respondents from the previously approved collection, with an approved burden of 1570 hours and 4435 respondents).

Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
IHC telephone interview-contacted	Pathologists	41	1	1/60	2
	Laboratory Directors	40			
	Laboratory Managers	40			
IHC telephone interview	Pathologists	20	1	20/60	13
	Laboratory Directors	10			
	Laboratory Managers	10			
IHC focus group invitation	Pathologists	34	1	5/60	17
	Pathology Chairs	33			
	Laboratory Directors	33			
	Laboratory Managers	34			
	Laboratory Supervisors	33			
	Histotechnologists	33			
IHC focus group	Pathologists	24	1	1	24

	Pathology Chairs				
	Laboratory Directors				
	Laboratory Managers				
	Laboratory Supervisors				
	Histotechnologists				
				Total	56

B.

Including both telephone interviews and focus groups, the total new respondent costs will be $3,348.09, compared with the original OMB approved total respondent costs of $97,460.

Form Name	Type of Respondent	No. of Respond-ents	No. of Responses per Respond-ent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate*	Total Respond-ent Cost
IHC telephone interview-contacted	Pathologists	41	1	1/60	1	$84.52	$84.52
	Laboratory Directors	40	1	1/60	1	$51.23	$51.23
	Laboratory Managers	40	1	1/60	1	$37.76	$37.76
IHC telephone interview	Pathologists	20	1	20/60	7	$84.52	$592.00
	Laboratory Directors	10	1	20/60	3	$51.23	$154.00
	Laboratory Managers	10	1	20/60	3	$37.76	$113.00
IHC focus group invitation	Pathologists	34	1	5/60	3	$84.52	$257.56
	Pathology Chairs	33	1	5/60	3	$84.52	$257.56
	Laboratory Directors	33	1	5/60	3	$51.23	$153.69
	Laboratory Managers	34	1	5/60	3	$37.76	$113.23
	Laboratory Supervisors	33	1	5/60	3	$37.76	$113.23
	Histotechnologists	33	1	5/60	3	$28.77	$86.31
IHC focus group	Pathologists	4	1	1	4	$84.52	$338.00
	Pathology Chairs	4	1	1	4	$84.52	$338.00
	Laboratory Directors	4	1	1	4	$51.23	$205.00

	Laboratory Managers	4	1	1	4	$37.76	$151.00
	Laboratory Supervisors	4	1	1	4	$37.76	$151.00
	Histotechnologists	4	1	1	4	$28.77	$115.00
						Total	$3,348.09

* The hourly wage rate for Pathologists, in the above table, was taken from the 2013 Bureau of Labor Statistics website. The hourly wage rate for Pathology Chairs, in the above table, is comparable to that for a Pathologist. The hourly wage rate for Laboratory Directors, Laboratory Managers, and Laboratory Supervisors, in the above table, was taken from http://www.mloonline.com/ebook/201403/resources/6.htm. Similarly, because histotechnologists' hourly wage rate is comparable to that for a medical laboratory scientist (MLS), a MLS hourly wage rate was used for histotechnologists in the above table, and was taken from http://www.mloonline.com/ebook/201403/resources/6.htm.
The hourly wage rate for laboratory directors, managers, supervisors, and histotechnologists 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. 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 (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/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) and one individual with GSA pay scale of Grade 14 (contributing 10% 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%	$135, 656
Medical Officer	5%	$210, 704
Total Annual Cost		$24, 101

In addition, the CAP will be using CDC funds awarded as part of the cooperative agreement to provide breakfast and lunch to 24 focus group participants. The estimated per person costs are $50 and $60 for breakfast and lunch, respectively. The total cost for the light meals is $1320 ($50x12 + $60x12).

The overall annualized cost to the federal government is $25,421.

15. Explanation for Program Changes or Adjustments

The telephone interview script **(Attachment C1)** and the focus group discussions **(Attachment D)** are focused on the qualitative aspect, allowing a fuller exploration of the factors that underlie the adoption or non-adoption reasons and rates by laboratory professionals. Specifically, the telephone interview is designed to examine the knowledge, attitude and behavior barriers regarding adoption and uptake of clinical practice guidelines, specifically the *Principles of Analytic Validation of Immunohistochemical Assays* published by CAP in 2014. The focus groups will allow the CAP to further explore the usage of CAP tools and resources (toolkit) that may help facilitate adoption of the IHC LPG and improve the LPG and toolkit for future revisions. This will help the CAP to identify the facilitators and barriers to laboratory professionals' awareness and familiarity of, and agreement with the guideline recommendations as well as the self-efficacy (empowerment to effect the change), outcome expectancy (the belief that there will be a change due to adoption of the recommendation) and ability to overcome previous practice inertia (collectively known as knowledge, attitude and behavior barriers). The CAP is interested in knowing whether the guideline provided clarification on parameters for the initial validation and re-validation IHC testing procedures and what additional tools and resources would help with implementation. With this information and identification of any external factors to implementation, such as cost, staffing resources etc., CAP will be able to position themselves to help influence laboratory guideline adoption to ensure optimal testing conditions and improve patient care.

This revision includes three types of laboratory professionals who were not included in the original OMB-approved submission: pathology chairs, laboratory supervisors, and histotechnologists. Because the OMB-approved IHC post-survey has been completed, this request for OMB approval of additional data collection (telephone interviews and focus groups) is a reduction of burden.

16. Plans for Tabulation and Publication and Project Time Schedule

Activity	**Time Schedule**
Telephone Interviews Conducted	1-4 weeks following OMB clearance
Focus Group Discussions Conducted	2-3 months following OMB clearance
Analysis of Qualitative Information Gathered	4-6 months following OMB clearance
Publication	12-16 months following OMB clearance

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.