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

College of American Pathologists

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Request for Approval of Revised Data Collection

Supporting Statement B

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Table of Contents

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

A random sample of 121 of the 3,335 respondents who returned completed IHC post-surveys will be invited **(Attachment C)** to participate in a telephone interview **(Attachment C1)** until 40 total interviews are conducted. For the purposes of burden estimate and previous CAP experience, we anticipate that it will take approximately three calls to reach each laboratory professional who will voluntarily participate; thus, 121 laboratory professionals will be included in the pool. Also for the purposes of burden estimate, we anticipate that the individuals who complete the telephone interview will be comprised of approximately 20 pathologists, 10 laboratory directors, and 10 laboratory managers.

The CAP will attempt to obtain the list of American Society for Clinical Pathology (ASCP) registrants and cross-reference laboratory professionals from both the non-CAP PT customer laboratories and the CAP PT customers who returned the completed IHC post-survey in 2015 via a random sampling based on profession/job title to be invited to participate in one of the two in-person focus group (**Attachment D)** sessions. The 121 laboratory professionals contacted to participate in the telephone interview will not be included in the pool of focus group participants. For the purposes of burden estimate, it is anticipated that 200 laboratory professionals will be contacted **(Attachment E)** to determine their availability to participate in one of two focus group sessions. Among the 200 laboratory professionals contacted, only the 24 who are selected to participate in the focus group sessions will each be asked to read and submit a signed consent form **(Attachment F)** prior to the session. We anticipate that approximately 4 pathologists, 4 pathology chairs, and 4 laboratory directors will comprise one peer focus group and approximately 12 laboratory professionals (4 laboratory managers, 4 laboratory supervisors, and 4 histotechnologists) will comprise the other focus group session. The 24 individuals will be selected on "first-come" basis for their respective profession/job title categories.

2. Procedures for the Collection of Information

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 C1 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 is designed to collect opinions and perceptions of the laboratory professionals on the usefulness and/or difficulty in implementing the IHC LPG. If the interviewee is not aware of or familiar with the guideline (Topic 1 of the Script), Mr. Brooks 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, Mr. Brooks 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. Mr. Brooks 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. 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. Mr. Brooks 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. Mr. Brooks 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.

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. The CAP will screen 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 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.

The moderator/facilitator will a representative of Strategic Business Innovations and the note-takers will be CAP staff Ms. Rhona Souers and Ms. Lisa Fatheree. CDC staff Dr. Rex Astles will be an observer. CAP guideline author Dr. Patrick Fitzgibbons will also be present as CAP believes the collegial atmosphere will add to the participants' experience. No audio or video recording devices will be used in order to increase respect for participants' anonymity. 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)**. The moderator/facilitator will be Mr. Brooks and the note-takers will be CAP staff Ms. Rhona Souers and Ms. Lisa Fatheree. CDC staff Dr. Rex Astles will be an observer. CAP guideline author Dr. Patrick Fitzgibbons will also be present as CAP believes the collegial atmosphere will add to the participants' experience. No audio or video recording devices will be used in order to increase respect for participants' anonymity.

3. Methods to Maximize Response Rates and Deal with No Response

This section is not applicable to telephone interviews or in-person focus groups.

4. Tests of Procedures or Methods to be Undertaken

The CAP's experienced contractor, Strategic Business Innovations (SBI), will conduct pilot testing for the telephone interview and focus group session script with at least one pathologist and laboratory professional (laboratory manager, laboratory supervisor, or histotechnologist) from the institutions of either CAP's Guideline Metric Expert Panel (GMEP) and/or the CAP's Center Committee.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following provided consultation on telephone interview and focus group questions/probes design:

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Strategic Business Innovations will compile and Ms. Souers will analyze the telephone interview and focus group qualitative data. The contractor, Strategic Business Innovations, has worked in a variety of industries, but the last eight years has been heavily focused in the Life Sciences/Medical Industry. During that time, he has executed over 50 full scale primary research projects involving interviews (in person and over the phone) and supporting focus groups. Ms. Souers has worked for more than 20 years at the CAP on projects ranging from quality improvement studies to instrumentation validation tool development. Ms. Fatheree has worked more than 10 years at CAP originally working on cytology proficiency testing and educational products and now leading CAP's evidence-based guideline development and implementation programs.