Laboratory Medicine Best Practices Project

Request for OMB Approval of a New Data Collection
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Contact:

Anne O'Connor
Office of Policy and Planning
National Center for Preparedness, Detection, and Control of Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS C-12
Atlanta, Georgia 30333
Phone: (404) 639-1042
Fax: (404) 639-3039
Email: aoconnor@cdc.gov

Laboratory Medicine Best Practices Project

The Centers for Disease Control and Prevention (CDC) is requesting Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 for a new collection of information from healthcare organizations about laboratory medicine unpublished studies or in house assessments that demonstrate practice effectiveness. CDC is requesting three year approval for this information collection request.

A. Justification

1. Circumstances Making the Collection of Information Necessary

In response to the Institute of Medicine's call to improve quality in medicine (*To Err is Human*, 2000), the Centers for Disease Control and Prevention (CDC) has sponsored an initiative (Laboratory Medicine Best Practices) to develop and pilot test new review and grading methods for completing systematic reviews of effective health care quality improvement and patient safety practices associated with laboratory medicine pre- and post analytic phases of testing. While evidence-based approaches such as systematic reviews for decision-making have become standard in healthcare, this has been limited in laboratory medicine due in part to the limited quality and quantity of published literature. Systematic reviews involve looking at and evaluating all the evidence on a particular topic, not just the evidence found in a few papers published in large, easy-to-find journals and explicitly linking public health or clinical practice recommendations to scientific evidence of the effectiveness and/or other characteristics of such practices. Currently, no single-evidence-based model for recommending practices in laboratory medicine exists, although the number of laboratories operating in the United States and the volume of laboratory tests available warrant such a model. Adopting an evidence-based approach in Laboratory Medicine:

- facilitates practice decisions being based on best information available vs. conforming to established rituals
- introduces effective new procedures and practices
- attest or validate existing practices
- promotes more efficient use of resources
- supports the patient care process
- helps ensure the retrieval of up-to-date and reliable information about what works and doesn't work in laboratory medicine

The Laboratory Medicine Best Practices (LMBP) project was initiated in October 2006, when CDC convened the Laboratory Medicine Best Practices Workgroup (Workgroup), a multidisciplinary panel comprising experts in several fields including laboratory medicine, clinical medicine, health services research, and health care performance measurement. The primary objective of the LMBP project is to develop a science-based program relying on newly developed and tested methods for producing systematic evidence effectiveness reviews related to pre- and post-analytic laboratory medicine practices for multiple topic areas. To date, project work has been completed over three phases.

In Phase 1 (October 2006-September 2007), CDC staff supported a proof of concept test of new systematic review methods for conducting quality improvement evidence reviews to identify pre-and post-analytic practices that are effective at improving laboratory medicine. The LMBP review methods were developed by adapting validated protocols from several organizations involved with public health and healthcare-related evidence reviews and recommendations (US Preventative Taskforce, the Agency for Healthcare Research and Quality and The Guide to Preventative Services). The conduct of a pilot evidence review on patient specimen identification indicated insufficient quality and number of studies for completing systematic evidence reviews of laboratory medicine practice effectiveness, and hence for making evidence-based recommendations regarding implementation of relevant practices. A finding from Phase 1 work indicated that laboratories would be unlikely to publish studies demonstrating practice effectiveness in the peer reviewed literature but that they routinely conducted quality improvement projects and had relevant data for completion of evidence reviews. These results were considered likely to be generalizable to most potential LMBP review topics. As a result of this outcome and the consensus of the Workgroup, Phases 2 and 3 of the LMBP project focused on the availability of unpublished studies routinely performed by healthcare organizations for the purposes of quality assurance, process improvement and/or accreditation documentation.

Phase 2 (September 2007-November 2008) and Phase 3 (December 2008 – September 2009), involved the pilot testing of developed LMBP methods to obtain, review, and critically appraise completed published and unpublished studies. These methods include written rating guides to evaluate and rate study quality and effect size, assess the overall strength of a body of evidence for a given practice, and present evaluation findings. During Phase 2, systematic evidence reviews were conducted, one focused on effective practices to reduce patient specimen identification errors and the other on effective practices to improve the timeliness and accuracy of critical values reporting. Completion of these evidence reviews entailed a comprehensive search of the published literature for studies relevant to the respective review questions. To test the feasibility of collecting unpublished data from healthcare organizations, sites with potentially relevant data were identified (through personal knowledge of LMBP Workgroup and Expert Panel members) and invited to submit available completed quality improvement studies that demonstrated impact of a practice relevant to the review. Invited sites submitted de-identified data only in any format they had accessible. One such example is a quality improvement study that examined the impact of bar-coding on improving accurate specimen identification.
A total of 7 sites were included in the pilot test. Written submissions were accepted by email by designated CDC project staff and reviewed by the project review team. A Phase 2 recommendation of the LMBP Workgroup and pilot test participants was the development of a standardized data collection form that would provide guidance to evidence review participants on documentation of quality improvement projects. Phase 3 pilot testing was focused on the utility of a standardized data collection form (LMBP Data Submission form). During this phase, three reviews were conducted and less than 9 participants (sites with unpublished data relevant to one of the review topics) were invited to submit data using a draft LMBP Data Submission form. Completed forms were emailed to a designated staff person and then reviewed by the CDC project review team. Participants submitting data were asked to comment on length of time to complete the submission form, clarity of the instructions and ease of use. Two of the participating sites previously participated in the Phase 2 pilot test and had submitted data without using the LMBP Data Submission form. Phase 3 findings were consistent with Phase 1 findings

that data from unpublished quality improvement studies could supplement data from published studies in laboratory medicine evidence reviews.

The objective for successive LMBP systematic evidence reviews is to allow the submission of data from unpublished quality improvement studies/projects in order to conduct comparisons of practices and inform those who use and pay for laboratory services about which practices are effective. The information will be collected using the LMBP Data Submission Form (Attachment C). Results from annual LMBP evidence reviews will be published on the LMBP website and provide a national-level information hub to foster the dissemination and implementation of evidence-based laboratory medicine practices.

This study is authorized under Section 301 of the Public Health Service Act (42 USC 241) (Attachment A).

Privacy Impact Assessment

Overview of the Data Collection System

CDC will collect information using an online LMBP Data Submission Form (Attachment C). Submissions will come from a variety of care settings including inpatient facilities, outpatient facilities, independent laboratories, and community care settings. Respondents will be asked to register their facility or organization online and will be able to access the Submission form online. Only online submissions will be accepted. Upon completion of the submission form, respondents will be able to electronically submit the completed form to the designated project staff. The data submission form will accommodate submissions for multiple topics.

Only the minimum amount of information needed for enrollment purposes (name, phone number, email, and organization name) will be collected. The online data collection form is organized by six sections:

- Section one addresses organization demographics (i.e. facility type, total annual testing volume)
- Section two requests information on the description and implementation of a laboratory practice including the duration and resources needed
- Section three addresses outcome measures used to assess the impact of the practice and results of the study
- Section four addresses implementation considerations for sustaining candidate practices
- Section five addresses what is needed to sustain the practice over time
- Section six provides a mechanism for respondents to submit suggestions for future reviews.

The information collected will be maintained at the CDC for at least 7 years.

Items of Information to be Collected

No patient-specific or personal health information is being collected. Participants are asked to submit de-identified data and can self select their organization to be anonymous in published summaries of evidence reviews. Section I. of the submission form collects information on organization demographics (organization type, number of beds, if hospital, total annual testing volume). Other information collected relates to description of the practice implemented for quality improvement, how the impact of this practice was assessed, and the results/findings of the implementation (Attachment C). Information will be collected on pre- and post analytic laboratory practices. It is anticipated that a variety of healthcare organizations will submit data including, medical centers, hospitals, outpatient laboratories and independent/commercial laboratories. Solicitations for submission will be posted online and also publicized at professional conferences as well as through the Laboratory Medicine Best Practices (LMBP) Network.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Respondents will only be able to submit their information online using the LMBP Data Submission form. This will be accessible at an established website. This website consists of general information about the website and voluntary participation in the LMBP network. No content is directed at children under 13 years of age. The contractor to this project, Battelle Memorial Institute (Battelle) will maintain the website and online data collection as well as provide support to respondents. Battelle will maintain rules of conduct pertaining to the privacy of information collected from respondents. Cookies will not be used to collect any identifying information from users or to track user activities beyond the web site. Copies of cookies on our web site after you leave our web site. Only Battelle and CDC staff with assigned responsibility to the LMBP project will have access to the information collected through the website. All facility data will be protected through access control, encryption during transmission, and personnel and physical facility security policies and procedures. Security controls will ensure availability of data by detecting and defending against intrusive attacks, such as viruses, malware, and denial of service; regular backups of data; disaster recovery and contingency planning; and patch management and automatic upgrades of data systems. Hard copies of quality improvement projects/studies will be secured in locked storage cabinets and access strictly limited.

2. Purpose and Use of Information Collection

The purpose of information collection is to obtain completed unpublished quality improvement studies/assessments carried out by healthcare organizations (laboratories, hospitals, clinics), in order to conduct quality improvement evidence reviews. The purpose of LMBP evidence reviews is to identify pre-and post-analytic practices that are effective at improving laboratory medicine.

Traditionally, systematic evidence reviews rely on published peer-reviewed literature, but in laboratory medicine, published evidence of practice effectiveness is limited. The objective for successive LMBP systematic evidence reviews is to supplement published evidence with unpublished data not accessible by conventional means in order to provide sufficient evidence

for completion of these reviews of practice effectiveness. Laboratory medicine is a critical component of the healthcare system that is burdened by variability in practices. This information will benefit respondents through an exchange of information about practices in laboratories and support information related to the implementation and use of these practices in their settings.

To minimize the burden on respondents and maintain consistency with published evidence retrieved for completion of evidence reviews, only previously completed studies will be requested (i.e., no new data) from Network members. No personal health information concerning patients will be collected. Information submitted via the online LMBP Data Submission form will be screened by at least two independent reviewers using pre-specified criteria also applied to studies obtained from peer-reviewed published literature. Study information from submissions that meet the inclusion criteria for LMBP evidence reviews will be aggregated and summarized in a standardized format (Attachment D, Evidence Summary Table Format**)**. Summarized studies are further evaluated by the DLS review team based on the following criteria:

- Potential impact on relevant outcome measures related to at least one Institute of Medicine health care quality domain (Safety, Timeliness, Effectiveness, Efficiency, Equity, and Patient-centeredness).
- In use and available for adoption,
- Reproducible in comparable settings,
- Addresses a defined/definable group of patients

The CDC Review team utilizes the evidence review summary tables are to apply ratings for study quality as well as the impact of a study. These ratings (Attachment E, Study Rating Guide) are then reviewed by expert panelists and used to draft best practice recommendations for practices that demonstrate effectiveness. Healthcare organizations and facilities (laboratory, hospital, clinic) will be able to use these reviews for self evaluation and may adjust their procedures/practices to improve clinical care. It is anticipated that data collection will improve the knowledge base within the laboratory community, provide a resource for the determination of best practices and dissemination of findings that support the improvement of patient care and efficient use of resources.

Privacy Impact Assessment Information

The purpose of this information collection is to obtain completed unpublished quality improvement studies/assessments carried out by healthcare organizations (laboratories, hospitals, clinics) in order to conduct a systematic review of the effectiveness of laboratory medicine practices. After conducting its review, CDC will post the documents on a website for Network members to view. Members will be able to use these documents in their own facilities to improve laboratory practice. Since no sensitive information is being collected, the data collection will have little or no effect on the respondent's privacy if there were a breach in confidentiality. No information in identifiable form is being collected.

3. Use of Improved Information Technology and Burden Reduction

One hundred percent of responses will be electronic submissions of information related to completed quality improvement studies/projects conducted. Only electronic submissions of data will be accepted. Only the minimum amount of information needed will be collected. The LMBP Data Submission Form includes guidance on how to prepare submissions. Respondents may print this guidance to help with collations of information and to reduce the time it takes to complete their practice submission.

4. Efforts to Identify Duplication and Use of Similar Information

In order to ensure that this information collection will not duplicate information otherwise accessible to CDC, CDC conducted an extensive search of published literature (October 2006 – October 2008), which indicated insufficient number and quality of studies for completing systematic evidence reviews of laboratory medicine practices. CDC also consulted with LMBP Workgroup members and other professional organizations regarding the existence of other similar information collections and made inquires at national conferences of interest to the laboratory community. No systematic evidence reviews of laboratory medicine practices are currently conducted utilizing both published and unpublished data.

5. Impact on Small Businesses or Other Small Entities

Some of the laboratories, clinics and other facilities which may submit data may be classified as small business entities. Participation in submissions is voluntary. Respondents are only expected to report information for which they already have maintained records therefore their voluntary participation involves no additional record-keeping. The data collection methods are designed to minimize burden on all participants.

6. Consequences of Collecting the Information Less Frequently

Respondents will be asked to submit available data at least annually in order to disseminate timely LMBP review findings and maintain up-to-date database information. There are no legal obstacles to reduce the burden. Without this data collection effort, a central source for information regarding the comparative effectiveness of pre and post laboratory medicine practices will not be available to those who use, implement or pay for laboratory services.

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

This request fully complies with the regulation 5 CFR 1320.5. No special circumstances are planned or intended for the participants/submitters.

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

A. A 60 day Federal register notice was published in the Federal Register on July 21, 2009, Volume 74, No. 138, pages 3870-3871 (see Attachment B). CDC has received one request to review the supporting statement and supporting documentation. CDC complied with the request on July 27, 2009. A copy of the comment and response is found in Attachment G.

B. In development of the LMBP Submission Form, CDC consulted with the following persons to obtain their views on the availability of data, frequency of collection, clarity of instructions for data submission and record-keeping:

Jim Derzon, PhD, Senior Evaluation Specialist
Battelle Centers for Public Health Research and Evaluation,
2101 Wilson Blvd. #800
Arlington, VA, 22201-3008
v. 703.248.1640, c. 703.915.1876 fax. 703.527.5640
derzonj@battelle.org

Edward Liebow, PhD, Site Director
Battelle Centers for Public Health Research and Evaluation
1100 Dexter Avenue North, Suite 400
Seattle, WA 98109
v. 206.528.3155, fax: 614.458.6683
LiebowE@battelle.org

Paul Epner, MEd, MBA
Laboratory Practice Consultant to
Battelle Centers for Public Health Research and Evaluation
1100 Dexter Avenue North, Suite 400
Seattle, WA 98109
v. 847-508-2818
pepner@chicagobooth.edu

Diana Mass, MA, MT, CLS
Director and Professor of Clinical Laboratory Sciences
Arizona State University
Jem16@au.edu

Robert H. Christenson, PhD, DABCC, FACB
Professor of Pathology and Medical Research Technology
University of Maryland Medical Center
rchristenson@umm.edu

The LMBP Workgroup Roster provides a list of other experts who have been engaged during the developmental aspects of the Laboratory Medicine Best Practices project (Attachment F).

9. Explanations of Any Payment or Gift to Respondents
No remuneration will be paid to respondents

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is not applicable. This data collection pertains to organizational or facility information and not individuals or households. No patient health information is being collected. A standard for evidence reviews is the publication of evidence summaries (Attachment D, Evidence Summary Table) which details all studies retrieved and evaluated on a similar topic as well as lists the principal investigators information and the name of the facility/healthcare organization submitting the study. Healthcare organizations that submit data to LMBP evidence reviews have the option to remain anonymous in publications or summaries describing systematic review findings for a topic area. No contact information will be listed on any reports or summaries of evidence review findings. CDC has applied for assurance of confidentiality (308d) for this data collection as some potential participants seeking to participate in the LMBP data collection have conveyed that they would be limited as to what data they could release by their legal counsel.

Data collection management will be performed under contract by Battelle Memorial Institute (Battelle). Only designated Battelle LMBP project staff will have access to submitter's name and contact information. CDC review team staff will have access only to de-identified study information provided by the submitter for completing of evidence reviews. Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Hard copies of data submissions will be secured in locked stored cabinets and access strictly limited. Battelle's cybersecurity policies are compliant with restricting access to business information and include the use of passwords on all computing devices used to store business information, auto-locking on all computing devices after 10 mins of idle time and network passwords which are changed at least every six months. Staff is required to protect sensitive information during transmission or transit. Data must be encrypted during transmission over the internet, transfer by digital media, and while stored on portable devices. Battelle has implemented an SSL encrypted Secure File Transfer application to send large data files over the Internet securely. This file exchange can be used by all Battelle staff to exchange files between staff and/or external recipients. The link may be shared with contractors, clients, partners, etc. All uploaded files are encrypted in transit and scanned for viruses. The Battelle IT staff is responsible for ensuring that adequate backup and recovery procedures are in place to ensure that accidental or natural occurrences will not result in loss of project data. At a minimum, these procedures will include two (2) backup copies of the submission database and backups made after major updates to the database. Websites that are connected to Battelle's network are required to meet specific infrastructure requirements including:

Firewall—A firewall is required for connections from Battelle facilities to non-Battelle controlled networks, including the Internet.

Wireless LAN Access Points—Wireless LAN Access Points are prohibited without explicit approval.

Privacy Impact Assessment Information

A. This submission has been reviewed by ICRO, who has determined that the Privacy Act does not apply.

B. The following technical, physical and administrative safeguards will be in place.
Submitted data will be protected through access control, encryption during transmission, and personnel and physical facility security policies and procedures.
Only designated Battelle LMBP project staff will have access to submitter's name and contact information. CDC review team staff will have access only to de-identified study information provided by the submitter for completing of evidence reviews.
Access to submitted data will be limited through the use passwords on all computing devices used to store business information, auto-locking on all computing devices after 10 mins of idle time and the use of network passwords which are changed at least every six months.
Hard copies of data submissions will be secured in locked stored cabinets and access strictly limited.
Hard copies used by the CDC Review Team will be secured in locked stored cabinets and shredded after completion of evidence reviews.

C. No consent forms will be used. Respondents voluntarily sign up to register for the LMBP Network and for submittal of information. Information pertaining to intended use of the information submitted and plans for dissemination of findings will be posted to the website www.futurelabmedicine.org

D. Participants will be informed at the time of registering for participation in the LMBP Network and indicating interest in submitting data, that their participation is voluntary.

11. Justification for Sensitive Questions
No questions of a sensitive nature being asked.

12. Estimates of Annualized Burden Hours and Costs

A. Solicitations for submissions of unpublished studies will be made at professional meetings, online through the Laboratory Medicine Best Practices Network and through educational sessions being conducted by CDC in 2010. CDC anticipates that 150 responses will be received during the first year of data collection. It is anticipated that a variety of healthcare organizations will submit data including, medical centers, hospitals, outpatient laboratories and independent/commercial laboratories. Submissions will be requested at least annually. Consultations with six potential respondents were conducted in July 2009 to estimate the timing to complete the Data Submission form. The estimated annualized burden hours are 40 minutes per respondent to complete the data submission form.

Estimated Annualized Burden Hours

Respondents	No. of respondents	No. of Responses per respondent	Average Burden per response (in hours)	Total Burden (in hours)*
LMBP Data Submission form	150	1	55/60	138

*Total burden hours per form = number of respondents times number of responses per respondent times the burden per response.

B. The actual cost to the respondent's organization will depend on the hourly wage of individual respondents. It is anticipated that the majority of respondents will be Medical Technologists and also include Lab Supervisors or Pathologists. According to the American Society for Clinical Pathology's 2005 Wage and Vacancy Survey, the median income for Medical Technologists is $18 per hour, Lab Supervisors is $27 per hour and Pathologists is $80 per hour.

Type Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Medical technologist	54	$18.00	$972.00
Lab Supervisor	20	$27.00	$540.00
Pathologist	26	$80.00	$2080.00
Total			$3,592.00

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

There are no capital or start-up costs for respondents.

14. Annualized Cost to the Government

The costs to the Federal government consist of contractual costs and the time of two health scientists who oversee the contract and facilitate the review by Workgroup members and subsequent posting on the Network website.

Batelle contract - $100,000 – online tool and support
Project Officer – 20% of GS-14-5: $18,915
Health Scientist – 20% of GS-12-5: $13,460

Total Federal Government cost: $132,375

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will be used to complete LMBP evidence reviews. Information will be aggregated and standardized for the purpose of rating the study quality and impact of implemented practices (rating of the effect size of findings). Descriptive statistics will be completed by Battelle staff. Aggregate data regarding the facility type of respondents and annual testing volume will be reported. The results of the LMBP evidence reviews will be published through a report and made public online as well as shared by email with Laboratory Medicine Best Practices network participants. The results will also be published in peer reviewed journals by CDC project officers. CDC anticipates 3 submission periods over the 3 year approval period.

A. 16-1 Project Time Schedule	
Activity	**Time Schedule**
Submission period for unpublished studies	1 month after OMB approval
Submission Period Closes	4 months after OMB approval
Analysis of data	5 months after OMB approval
Report/Publication	6 months after OMB approval

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

Approval is not requested to not display OMB expiration date.

18. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Collections of Information Employing Statistical Methods

This data collection does not involve statistical methods.

1. Respondent Universe and Sampling Methods

The potential respondent universe is inclusive of medical centers, hospitals, independent laboratories, outpatient laboratories and physician office laboratories. CDC is estimating that approximately 150 sites will voluntarily enroll in the LMBP Network and submit data. The results of evidence reviews utilizing the information gained from data collection will be available to all LMBP Network enrollees and associated organizations through public domain.

2. Procedures for the Collection of Information

Data will be collected from voluntary registrants of the Laboratory Medicine Best Practices (LMBP) network who indicate that they would like to contribute data. Data will also be solicited from sites identified through literature searches of articles, and conference proceedings. Trained reviewers will screen submitted information by applying pre-determined criteria. All studies which meet the inclusion criteria will be aggregated using Evidence Summary tables.

3. Methods to maximize response Rates and deal with Nonresponse

A communications and outreach strategy has been developed to publicize the LMBP project and data collection needs. This involves outreach through presentations to professional laboratory organizations/associations, and email to voluntary registrants of the LMBP Network, and presentations at major laboratory conferences including the Clinical Laboratory Management Association (CLMA) and the American Association for Clinical Chemistry (AACC) annual conferences. The LMBP network will be established for information exchange and solely as a resource for unpublished studies.

4. Tests of procedures or Methods to be Undertaken

The LMBP Data Submission form was developed by a multidisciplinary team inclusive of expertise in survey design, statistics, laboratory medicine, public health, health education, economics, health systems research and evaluation. The comments and advice from team members were incorporated into the submission form design. The LMBP Data Submission form was also reviewed by public health scientists from CDC with content expertise in laboratory medicine and pilot tested with six potential respondents in order to refine questions, minimize burden and improve the utility of the form. Revised questions were incorporated based on the feedback from the pilot testers and consultants.

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

The LMBP Data Submission form was designed by:

Jim Derzon, PhD, Senior Evaluation Specialist
Battelle Centers for Public Health Research and Evaluation,
2101 Wilson Blvd. #800
Arlington, VA, 22201-3008
v. 703.248.1640, c. 703.915.1876 fax. 703.527.5640
derzonj@battelle.org

Edward Liebow, PhD, Site Director
Battelle Centers for Public Health Research and Evaluation
1100 Dexter Avenue North, Suite 400
Seattle, WA 98109
v. 206.528.3155, fax: 614.458.6683
LiebowE@battelle.org

Paul Epner, MEd, MBA
Laboratory Practice Consultant to
Battelle Centers for Public Health Research and Evaluation
1100 Dexter Avenue North, Suite 400
Seattle, WA 98109
v. 847-508-2818
pepner@chicagobooth.edu

Susan R. Snyder, PhD, MBA
Health Economist
1600 Clifton Road NE, MS G-23
Atlanta, GA 30333
v. 404-498-2245
ssnyder@cdc.gov

Colleen Shaw, MPH
Health Scientist, CDC
1600 Clifton Road NE, MS G-23
Atlanta, GA 30333
v. 404-498-2244
CSShaw@cdc.gov

Malaika Washington, MSPH
Orise Fellow, CDC
1600 Clifton Road NE, MS G-23
Atlanta, GA 30333
v. 404-498-2247
pzp9@cdc.gov

The Contractor for the Laboratory Medicine Best Practices project is:

Battelle Memorial Institute
Edward Liebow, PhD, Site Director
Battelle Centers for Public Health Research and Evaluation
1100 Dexter Avenue North, Suite 400
Seattle, WA 98109
v. 206.528.3155, fax: 614.458.6683
LiebowE@battelle.org

The Statistical Consultant is:

Jim Derzon, PhD, Senior Evaluation Specialist
Battelle Centers for Public Health Research and Evaluation,
2101 Wilson Blvd. #800

Arlington, VA, 22201-3008
v. 703.248.1640, c. 703.915.1876 fax. 703.527.5640
derzonj@battelle.org

List of Attachments

A. Authorizing legislation

B. 60 day Federal Register Notice

C. LMBP Data Submission Form

D. LMBP Evidence Summary Table Format

E. LMBP Rating Guide

F. LMBP Workgroup Roster

G. Public comment to 60 day FRN and CDC response