DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date

November 19, 2012

From

Associate Director for Science, CDC
Office of the Associate Director for Science

Subject

Authorization to grant 308(d) Assurance of Confidentiality Protection for the "The Laboratory Medicine Best Practices Research and Evaluation (LMBP)."

To

Stephen B. Thacker, MD
Director for the Office of Science, Epidemiology and Laboratory Services (OSELS)

This memo is to provide formal approval of OSELS's request to receive the authorization to assure confidentiality under Section 308(d) of the Public Health Service Act for the "The Laboratory Medicine Best Practices Research and Evaluation (LMBP).

The project has no prior history of receiving an Assurance of Confidentiality. For new and ongoing projects, CDC practice is that every five years, the program must apply for formal extension of the 308(d) authority. Please apply for the extension at least six months prior to November 2017.

Please use 42 USC 242(k), and 42 USC 242(m) as the legal references for information collection and protection.

If you have any questions, please contact Joseph Rush Jr. Confidentiality Administrator, at (404) 639-4772.

Tanja Popovic, MD, PhD, F(AAM), AM(AAFS)
Deputy Associate Director for Science, CDC

cc:
Elizabeth Leibach, EdD, MS, MLS, SBB

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)

Control No.: _____

REQUEST FOR AUTHORIZATION TO GIVE ASSURANCE OF CONFIDENTIALITY

UNDER SECTION 308(d) OF THE PUBLIC HEALTH SERVICE ACT

NOTE: Do not obtain signature on this form until OCSO and the Project Officer have agreed on final versions of the 308(d) Justification, Assurance, and Security Statement.
(See "Assurance of Confidentiality Application Procedure" for instructions on completing this form.)

1. REQUESTED BY:

Name of Project Officer/Principal Investigator:	Bldg/Rm No.:	MailStop:	Phone No.:
Elizabeth Leibach	2400 3201.07	G-23	(404)498-2245

Center/Institute/Office:	Division:
CDC/OSELS/LSPPPO	DLSS

Request Status:
☒ New ☐ Amended Request ☐ Extension Request

Period of time authorization needed for data collection:
(Indicate "ongoing" if project will continue indefinitely.)
From: 11/12 To: 10/2017 (ongoing)

Approval of Request by Center/Institute/Office Director or Designee:

Stephen B. Thacker, MD, OSELS Director — *Name and Organizational Title*
Stephen B Thacker — *Signature*
10/16/2012 — *Date*

2. TITLE OF PROJECT:

The Laboratory Medicine Best Practices Research and Evaluation (LMBP)

3. JUSTIFICATION STATEMENT:

Please attach the justification statement. *(See "Assurance of Confidentiality Application Procedure" for further details.)*

4. - FOR OCSO USE ONLY -

Transmitted to Confidentiality Review Group:

7/11/2012 — *Date*

Confidentiality Review Group recommends:

☑ Approval ☐ Disapproval

8/7/2012 — *Date*

-- ASSURANCE OF CONFIDENTIALITY IS AUTHORIZED --

Signature: for M Reynolds
CDC ASSOCIATE DIRECTOR FOR SCIENCE

11-20-12 — *Date*

THE LABORATORY MEDICINE BEST PRACTICES (LMBP) INITIATIVE

Laboratory Practices Research and Evaluation Branch (LREB)
Division of Laboratory Science and Standards (DLSS)
Office of Surveillance, Epidemiology, and Laboratory Services (OSELS)
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Atlanta, GA 30329

July 10, 2012; Elizabeth Kenimer Leibach, Ed.D., M.S., MLS, SBB

A. Purpose of Project

The purpose of the Laboratory Medicine Best Practices (LMBP) Initiative is to conduct systematic evidence reviews to assess the effectiveness of quality improvement practices in laboratory medicine. LMBP systematic reviews include the evaluation of studies from peer reviewed sources as well as the collection and evaluation of unpublished data from healthcare organizations (laboratories, hospitals and clinics) on quality improvement practices they have implemented in their settings.

In recent years several sentinel studies, including two reports from the Institute of Medicine (IOM) highlighted the need for improvements in the safety and quality of American healthcare. In response to the systemic shortcomings in healthcare quality identified by the IOM and others, evidence-based recommendations, guidelines, and quality measures have been developed in many fields of medicine. The Agency for Healthcare Research and Quality (AHRQ) compiles this information in its National Guidelines Clearinghouse and National Quality Measures Clearinghouse. Many disease-specific guidelines and quality measures for screening, diagnosis, treatment, and management include recommendations for laboratory testing. However, relatively few laboratory medicine guidelines and measures would meet AHRQ's inclusion criteria as they often lack substantiating support from peer-reviewed sources on evidence of effectiveness in practices that link laboratory medicine to health-related outcomes. These peer-reviewed single studies would be the source for published data for systematic review and meta-analysis directed toward quality improvement and identifying best practices in laboratory medicine.

Objectives

In laboratory medicine, previous efforts to develop guidelines, standards, policies, and best practice recommendations targeted specific sub-disciplines within the laboratory community. In laboratory medicine, most clinical practice is guided by expert opinion and consensus treatment and intervention pathways. It was apparent that a more systematic, comprehensive, and transparent approach to identifying, evaluating, and recommending best practices for the field of laboratory medicine was needed. 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), Office of Surveillance, Epidemiology and Laboratory Services (OSELS), Division of Laboratory Science and Standards (DLSS) sponsored the LMBP, to:

1. Develop evidence-based review and evaluation methods for identifying and evaluating pre- and post-analytic laboratory medicine practices that are effective at improving healthcare quality,

2. Utilize these methods to conduct quality improvement systematic reviews to include the analysis of unpublished data submitted by participating healthcare organizations,
3. Disseminate the findings of systematic reviews to the laboratory community, and
4. Evaluate the overall effectiveness of recommended laboratory medicine best practices through the adoption and measurement of the practices in quality improvement initiatives by participating healthcare organizations.

LMBP Initiative Implementation Phases

The Laboratory Medicine Best Practices (LMBP) Initiative was initiated in October 2006 and has been carried out via successive contracts with Battelle Memorial Institute's Center for Public Health Research and Evaluation (Battelle). The preliminary work activities were conducted over three phases:

Phase 1 (October 2006 – September 2007)

CDC staff supported a proof of concept test of new systematic review methods for conducting reviews of quality improvement interventions. 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 Preventive Taskforce, the Agency for Healthcare Research and Quality and The Guide to Community Preventive Services). A finding from Phase 1 work supported 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.

Phase 2 (September 2007 – November 2008)

Newly developed review and evaluation methods were pilot-tested through the conduct of three LMBP systematic reviews. The process for conducting the reviews involved: a) acquiring published studies, b) appraising studies by applying pre-determined screening criteria as well as established quality criteria, c) analyzing the data from the review and d) summarizing the findings of the review.

The purpose of the pilot was two-fold, first, to validate the methods for conducting systematic reviews and second to test the feasibility of collecting unpublished data from healthcare organizations. A total of seven laboratories representing various settings (community hospital, academic center etc.) provided data for the pilot-test. They provided data from relevant quality improvement studies in any format they had available. Study data were screened and rated by CDC and contract staff according to established LMBP review protocols. Laboratories which participated in the pilot-test were identified through personal knowledge of subject matter experts (LMBP Workgroup and Expert Panels) participating on the Initiative. A recommendation from phase two was for the development and pilot of a standardized form to collect unpublished data from healthcare organizations.

Phase 3 (December 2008 – September 2009)

Phase 3 activities involved the development and pilot of a standardized data collection form (Attachment A, LMBP Data Submission Form). An approval for use of the data submission form for data collection was granted by the federal Office of Management and Budget (OMB) on May 4, 2010. The pilot phase activity was finalized in 2009 with a Phase 3 report.

Current LMBP Activities

The current LMBP activities involve three evidence reviews with Battelle per year (Battelle is the contracting agent for CDC) and one evidence review per year in collaboration with CDC and a clinical laboratory organization, e.g. American Society for Microbiology. As part of each systematic evidence review, primary unpublished data will be submitted to CDC from healthcare organizations to supplement data obtained from publication from secondary and peer reviewed sources. The OMB approved LMBP Data Submission Form(s) is used to collect information from healthcare organizations on completed quality improvement projects. Submissions are screened by at least two trained independent CDC independent reviewers using pre-specified criteria also applied to studies obtained from peer-reviewed published literature. Study information from submissions are aggregated and standardized (Attachment B, Evidence Summary Table Format) for publication of review findings. The findings from annual LMBP systematic evidence reviews will be published in aggregate form in peer reviewed journals, e.g. *Clinical Chemistry, Journal of Clinical Biochemistry,* and on the LMBP Initiative website (accessible by the public) [www.futurelabmedicine.org].

The LMBP review team utilizes evidence review summary tables to apply ratings for study quality as well as the impact of a study. These ratings (Attachment C, Study Rating Guide) are then reviewed by expert panelists (volunteers who are experts germane to the systematic review topic) and used to draft best practice recommendations for practices that demonstrate effectiveness.

The LMBP Data Submission Form was adapted for web-based primary unpublished data entry and may only be accessed by submitters (organizations who want to submit data) on the LMBP website at www.futurelabmedicine.org . Organizations are able to register at the LMBP website for notifications and solicitations for data submission. Organizations cannot access submission other than their own. For each systematic review, email notifications are sent to website submitters when data are being accepted for a systematic review. Solicitations for data are also publicized at national professional meetings, through partner affiliations, and on the www.futurelabmedicine.org website. Potential organizational data submitters are identified through searches of journal data bases such as PubMed, conference proceedings, and through personal communication with subject matter experts. These potential data submitters are contacted and recruited by CDC and/or Battelle staff. Data collection, management and statistical analysis for all LMBP systematic reviews (09/01/2011 – 09/01/2014) is currently carried out under contract with the Battelle Memorial Institute's Center for Public Health Research and Evaluation (Battelle) and with participation by and oversight of CDC staff.

If the AoC is granted for LMBP, authorization would occur in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), Battelle is required to undertake safeguards for individuals and establishments to assure that confidentiality is maintained [Attachment E - Contractor's Pledge of 308(d) Confidentiality]. Battelle is required under contract to share the data obtained for each review with the CDC. CDC is the only organization to which data will be transferred; data will be published in aggregate only. CDC has access to identifiable data upon request and will continue to maintain clearance for full access.

The types of data collected are: organizational demographics (type of facility, number of beds, total testing volume), information related to the practice implemented, project/study characteristics such as when the study began and ended, and the findings of the study. All of the submissions from laboratory quality improvement measures will contain de-identified patient health information; some may contain facility information because some organization may choose not to remain anonymous. It is anticipated that diverse healthcare organizations representing the industry as a whole, to include medical centers, hospitals, outpatient laboratories, and independent/commercial laboratories, will submit quality improvement data.

B. Justification of Need

1. Extent to which the Assurance of Confidentiality is important to protection of the individual or institution.

LMBP systematic review findings are published in aggregate to demonstrate the effectiveness of interventions across settings. These findings are generalizable to all laboratories, large, small, public, and private, and represent the first evidence-based best practices open-source communication and dissemination point for laboratory medicine. Data collected for LMBP systematic evidence reviews are neither patient-specific nor considered protected health information under the HIPAA Privacy Rule; no reportable information (through state or federal fiat) is collected. However, organizational information related to error rates for various quality improvement practices is voluntarily submitted. The possibility exists that patients could identify participating organizations via demographic information (e.g., bed size, region of the country, time period, lab test or medical procedure involved) provided in the disseminated materials. Further, facilities likely to contribute data, such as hospitals, medical centers, and reference laboratories, have indicated the need for additional confidentiality protections such as an Assurance of Confidentiality which is often required by their Institutional Review Boards for participation in voluntary data submission efforts. Lastly, some healthcare organizations will not submit their quality improvement data because they are concerned that provided organizational demographical data will lead to public disclosure of their current quality improvement protocols for laboratory best practices, therefore, potentially exposing them to legal liability. The Assurance of Confidentiality could assist in alleviating some of those concerns because the identity of the healthcare organization would be protected from compulsory disclosure.

The purpose of applying for an Assurance of Confidentiality for the LMBP Initiative is to have the ability to assure institutions contributing data for systematic reviews that the confidentiality of data provided will be protected. Because the LMBP Initiative includes voluntary collection of data about de-identified patients and healthcare institutions, all of the data submitted are

considered sensitive and are treated as such. Compromise of these sensitive data would undermine the usefulness of LMBP efforts to provide actionable best practices for the laboratory community and other national and international organizations recommending medical practice guidelines that might choose to include LMBP recommendations in development of their positions.

2. Describe why/if the individual or institution will not furnish or permit access to the information unless an Assurance of Confidentiality is issued.

A primary objective of the LMBP Initiative is to collect unpublished quality improvement data from healthcare organizations to supplement published study findings, discover effective interventions for quality improvement in laboratory medicine practice, and evaluate LMBP recommendations. Findings from previous pilot testing established that it is standard practice for laboratories to conduct quality improvement assessments but retain data for internal purposes rather than publish externally. Organizations are aware that an Assurance of Confidentiality is not currently in place; however, they have been informed that an application to obtain an Assurance is being submitted. It is unlikely that participation by laboratories in this important LMBP effort will continue without an Assurance of Confidentiality. Organizations have expressed concern that results published from a systematic review could potentially identify their organizations. If these results are not understood as quality improvement, they could potentially damage their reputations in the laboratory medicine community, impact their competitive position among their peer institutions, and expose them to legal liability. Over half of institutions solicited for data communicated with our staff that they would not be able to share study data without additional confidentiality protection for the data they provide. Therefore without the Assurance of Confidentiality, the only open source for high confidence data describing laboratory best practices would potentially be lost and quality-compromised at best.

3. Describe whether or not the information could be obtained with the same degree of reliability from sources that do not require an assurance.

An objective of the LMBP Initiative is to identify mechanisms for obtaining quality improvement study data to supplement data published in peer reviewed journals. Pilot studies confirmed that reliable data can be obtained from healthcare organizations as they routinely conduct quality improvement studies. However if most healthcare organizations choose not to submit unpublished data because of the lack of additional confidentiality protection, the resulting restricted sampling base can reduce the validity and reliability, and quality of and confidence in, the recommendations from LMBP review of best practices. Sources of unpublished laboratory quality improvement data, other than peer reviewed reports and laboratory-shared studies, have not been identified.

4. Describe how the information is essential to the success of the particular statistical or epidemiological project and is not duplicative of other information gathering activities of the Department of Health and Human Services.

The LMBP Initiative is leading an effort to bridge a long-standing gap between analytic accuracy (laboratorians' providing valid, actionable test results) and medical meaningfulness (providers'

understanding of what to do with them) by collaborating with diverse stakeholder organizations and partners to produce recommendations for best practices in laboratory medicine. Obtaining unpublished study data from healthcare organizations is integral to LMBP systematic reviews from which these recommendations generate. Recommendations from synthesized studies (both published and unpublished sources) provide guidance to healthcare providers in their decision-making processes regarding utilization of laboratory information. Findings from pilot systematic evidence reviews established the value of study data from a diverse number of healthcare organizations. An extensive literature search (October 2006- October 2008) did not identify other duplicate information gathering activities of the Department of Health and Human Services (DHHS). The LMBP Initiative has been registered with the DHHS National Public Health Surveillance and Biosurveillance Registry.

5. Describe how/if the issuance of the Assurance of Confidentiality might restrain CDC from carrying out any of its responsibilities.

It is not anticipated that the issuance of an Assurance of Confidentiality for the Laboratory Medicine Best Practice Initiative would in any manner restrain CDC from carrying out any of its responsibilities. Recommendations are drawn from published and unpublished patient-de-identified data, voluntarily submitted, not through identification of the specific sources.

6. Describe the advantages of assuring confidentiality and how they outweigh the disadvantages.

The issuance of an Assurance of Confidentiality for the LMBP Initiative promotes greater participation of healthcare organizations in systematic evidence reviews. Assuring formal confidentiality protection with an Assurance of Confidentiality will facilitate increased participation of healthcare organizations in LMBP systematic reviews and an improved and expanded knowledge base of evidence-based laboratory medicine quality improvement practices. There are no disadvantages of providing an Assurance of Confidentiality.

CDC Human Subjects Review:

As determined by the Acting ADS for the Division of Laboratory System, this performance improvement project is considered as "not qualifying as human subjects research" and therefore review by an IRB is not being sought. An IRB determination form is attached (Attachment H). The information to be accessed and used in this project is not individually identifiable, because neither of the following is true:

A. The identity of the participant (patient) is or may be readily ascertained by the investigator.
B. The identity of the participant (patient) is or may be readily associated with the information.

CDC ASSURANCE OF CONFIDENTIALITY

ASSURANCE OF CONFIDENTIALITY FOR THE LABORATORY MEDICINE BEST PRACTICES INITIATIVE IN THE DIVISION OF LABORATORY SCIENCE AND STANDARDS

An Assurance of Confidentiality is provided for participants of data collection by the Laboratory Medicine Best Practices Project (LMBP), sponsored by the proposed Office of Surveillance, Epidemiology, and Laboratory Services (OSELS), Laboratory Services Policy, Practice, and Program Office (LSPPPO), Division of Laboratory Science and Standards (DLSS), Laboratory Practice Evaluation Branch (LPEB), a component of the Centers for Disease Control and Prevention (CDC), an agency of the United States Department of Health and Human Services.

The purpose of the LMBP information collection is to obtain completed unpublished quality improvement studies/assessments carried out by healthcare organizations (laboratories, hospitals, clinics), in order to conduct systematic quality improvement evidence reviews and identify pre- and post- analytic interventions that improve patient safety and health outcomes. This information collection pertains to organizational or facility information and not individuals or households. No personal identifying information on individuals will be collected. Healthcare organizations that submit data have the option to remain anonymous in publications or summaries describing systematic review findings for a topic area. Information collected includes: organizational demographics (e.g. organization type, number of beds, if hospital, total annual testing volume), description of the practice implemented for quality improvement, how the impact of this practice was assessed, and the results/findings of the implementation. LMBP evidence review findings (collected from healthcare organizations, e.g., organization type, number of beds, practice type for quality improvement measures etc.) will be disseminated in aggregate format on the website www.futurelabmedicine.org, via trade newsletters, and in peer-review journals.

Information collected by CDC and/or its contractor under Section 306 of the Public Health Service (PHS) Act (42 USC 242k), as part of LMBP information collection that could permit direct or indirect identification of healthcare organizations and affiliated staff who perform testing practices, is collected with the guarantee that it will be held in confidence, will be used only for the purposes stated in this Assurance, and will not otherwise be disclosed or released without the consent of the individual or establishments in accordance with Section 308 (d) of the Public Health Service Act (42 U.S.C. 242m(d)). In particular, such information will not be disclosed to the public; to family members; to parties involved in civil, criminal, or administrative litigation, or for commercial purposes, to agencies of the federal, state, or local government. This protection lasts indefinitely, even past the death of participating parties and/or the closing or reorganizing of the participating healthcare organizations.

Information reported to CDC by Battelle will be used without identifiers for conducting evidence reviews and providing summaries that relate to the (1) effectiveness of studied practices/interventions, (2) relevant patient population, and (3) applicability of studied practices/interventions across healthcare settings and patient groups.

Information reported to CDC will be kept confidential. Only authorized employees of the LMBP project, their contractors, guest evaluators and fellows, visiting scientists, research interns and graduate students will have access to evidence review submissions in accordance with this Assurance. Authorized individuals are required to handle the information in accordance with procedures outlined in the Confidentiality Security Statement for the Laboratory Medicine Best Practices (LMBP) for Laboratory Practice Evaluation data, the "Nondisclosure Agreement (Attachment D) for federal personnel," the "LMBP Privacy Act Checklist (Attachment G)," and "Safeguards for Individuals and Establishments Against Invasions of Privacy (Attachment E)."

The assurance of confidentiality stated on LMBP data collection forms will read as follows and this will be located on the website:

> ***Assurance of Confidentiality:*** *The voluntarily provided information obtained in this data collection system that could permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).*

Confidentiality Security Statement
Laboratory Medicine Best Practices (LMBP) Initiative

Data collection, management and statistical analysis for all Laboratory Medicine Best Practices systematic reviews (09/01/2011 – 09/01/2014) is carried out under contract with the Battelle Memorial Institute's Center for Public Health Research and Evaluation (Battelle). Under contract Battelle maintains the related website, www.futurelabmedicine.org and web-based data collection. This includes issuing calls for data, addressing technical problems with the website, and providing technical assistance to data submitters. Only patient de-identified data are requested for LMBP reviews and no patient-specific or protected health information is collected. As outlined in the Contractors Pledge of 308(d) Confidentiality (Attachment E), Battelle is required to undertake listed safeguards for establishments to assure that confidentiality is maintained. This document will be provided to Battelle for signature by their employees working on the project.

Battelle will be required to maintain rules of conduct pertaining to the privacy of information collected. Hard copies of data submissions will be secured in locked stored cabinets and access strictly limited. Cookies will not be used to collect any identifying information from users or to track user activities beyond the website. Only designated Battelle LMBP project staff will have access to organizational information collected. CDC will have access to the identity of the organization upon request. Battelle's cyber security 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 minutes of idle time and network passwords which are changed at least every six months. The Battelle information technology 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: (a) the engagement of a firewall required for connections from Battelle facilities to non-Battelle controlled networks, including the Internet, and (b) the prohibition of the use of wireless LAN Access Points without explicit approval. (See Attachment F)

CDC staff interfacing with the Initiative will also be required to adhere to confidentiality safeguards. CDC staff will only have access to the data on through Battelle.

Privacy Impact Assessment Information

A. The LMBP Initiative protocol description has been reviewed by Information Collection Review Office, who has determined that the Privacy Act does not apply.
B. The following technical, physical and administrative safeguards will be in place:

a. Submitted data will be protected through access control, encryption during transmission, and personnel and physical facility security policies and procedures.
b. Only designated CDC and Battelle LMBP project staff will have access to submitters' names and contact information.
c. 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 minutes of idle time and the use of network passwords which are changed at least every six months.
d. Hard copies of data submissions will be secured in locked stored cabinets and access strictly limited. Data submissions and records related to data submissions are considered CDC property and will be retained in accordance with CDC Records Retention schedule. See section, "Records Disposition for the National Archives and Records Administration" below.
e. Hard copies used by the CDC Review Team will be secured in locked stored cabinets and disposed of after completion of evidence reviews and in accordance with applicable records schedules.

LMBP Initiative and contract staff are required to maintain and protect at all times the confidential records that may come into their presence and under their control. To assure that they are aware of this responsibility and the penalties for failing to comply, each member of the CDC and Battelle staff must read and sign a Nondisclosure Agreement (CDC 0.979) or the Contractor's Pledge of Confidentiality, respectively, assuring that all information identifying an individual healthcare institution that is subject to this Assurance will be kept confidential and will be used only for epidemiologic or statistical purposes.

Attachment D is the Nondisclosure Agreement that all DLSS Full-Time Equivalent (FTE) staff on the project will sign. The originals will be retained by DLSS. When confidentiality authorization is obtained, LMBP staff (current and future) will be required to attend an initial training session which will be conducted by the Office of Scientific Integrity at which the confidentiality procedures for the project will be discussed. Signed non CDC employee pledge of confidentiality agreements (Attachment I) will be obtained at this time and maintained on file.

Attachment E is the contractor's pledge of confidentiality, called "Safeguards for Individuals and Establishments against Invasion of Privacy." For LMBP contractors, currently Battelle, 308(d) clauses will be added to the contract and all contractor employees with access to the voluntarily provided data that are subject to this Assurance will be required to sign this contractor pledge. Originals of these documents will be retained by PGO with copies on file at DLSS.

Dissemination of Project Results:

LMBP contractors/subcontractors will supply confidential reports of results according to contract stipulations. Participating institution will receive no report from LMBP. The findings from annual LMBP systematic evidence reviews will be published in aggregate in peer reviewed

journals e.g. *Clinical Chemistry, Journal of Clinical Biochemistry,* and on the LMBP Initiative website [www.futurelabmedicine.org].

There are several primary intended uses for LMBP data:

1) Develop evidence-based review and evaluation methods for identifying and evaluating pre- and post-analytic laboratory medicine practices that are effective at improving healthcare quality which will assist in conducting quality improvement systematic reviews to include the analysis of unpublished data submitted by participating healthcare organizations.

2) Evaluate findings to determine effective interventions for quality improvement in laboratory medicine practice. The findings for laboratory quality improvements will assist in delineating protocols for laboratory best practices.

Records Disposition for the National Archives and Records Administration
After the end of the project, if the records are determined to be permanently valuable, a public use data tape will be sent to the National Achieves and Records Administration (NARA). This transfer will be done in accordance with the May 1996 agreement stating that CDC will transfer to NARA all permanent data sets in accordance with approved schedules contained in part IV of the CDC Records Control Schedule B 321, with the exception of identifying information collected under an assurance of confidentiality agreement as specified under the Public Health Service Act, Sections 301(d) and 308(d).

If 308(d) records for this project are being sent to the Federal Records Center for temporary storage (in which CDC maintains control of the data), they must be clearly identified as 308(d) protected records. The SF 135 should state: "This accession contains records protected by a confidentiality assurance under Section 308(d) of the PHS Act." The boxes should have a label stating: "This accession contains records protected by a confidentiality assurance under Section 308(d) of the PHS Act. The records can be released only to authorized staff from the Division of Laboratory Science and Standards (DLSS).

List of Attachments:

Attachment A: Laboratory Medicine Best Practice (LMBP) Submission Form
Attachment B: LMBP Evidence Summary Table Format
Attachment C: LMBP Guide to Rating Study Quality
Attachment D: LMBP Nondisclosure Agreement for Federal Personnel
Attachment E: LMBP Contractor's Pledge of 308 (d) Confidentiality Safeguards for Individuals and Establishments
Attachment F: Supplemental LMBP Confidentiality Security Statement
Attachment G: LMBP Privacy Act Checklist
Attachment H: IRB Determination
Attachment I: Non CDC employee pledge of confidentiality