

**06.1 HHS Privacy Impact Assessment (Form) / Botulism Database Primavera ProSight  
CDC PIA (April 2011)**

**PIA SUMMARY**

The following required questions with an asterisk (\*) represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget (OMB) and public posting in accordance with OMB Memorandum (M) 03-22.

Note: If a question or its response is not applicable, please answer "N/A" to that question where possible. If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of personally identifiable information (PII). If no PII is contained in the system, please answer questions in the PIA Summary Tab and then promote the PIA to the Senior Official for Privacy who will authorize the PIA. If this system contains PII, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

**2 Summary of PIA Required Questions**

\*Is this a new PIA?

Yes

If this is an existing PIA, please provide a reason for revision:

\*1. Date of this Submission:

January 11, 2013

\*2. OPDIV Name:

CDC

\*3. Unique Project Identifier (UPI) Number for current fiscal year:

2190 (esc entry)

\*4. Privacy Act System of Records Notice (SORN) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):

09-20-0113

\*5. OMB Information Collection Approval Number:

N/A

\*6. Other Identifying Number(s):

N/A

\*7. System Name (Align with system item name):

Botulism Database

\*9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:

**Point of Contact Information**

POC Name

Katie Fullerton

\*10. Provide an overview of the system:

Note: If SSN's (Social Security Numbers) will be collected, maintained (stored), disseminated and/or pass through within any database(s), record(s), file(s) or website(s) hosted by this system you must complete and submit **Attachment A - SSN Elimination or Usage Approval Request** located at <http://intranet.cdc.gov/ociso/pandp/policy.html>

Note: According to OMB 07-16M, All agencies MUST participate in government-wide effort to eliminate unnecessary use of and explore alternatives to agency use of Social Security Numbers as a personal identifier for both Federal employees and in Federal programs.

The Botulism System in the Enteric Diseases Epidemiology Branch (EDEB) comprises three databases. The database known as "Master Line List 1899\_2010.mdb" is used for case surveillance, collects no PII, and is in a secured folder on the EDEB National Surveillance share drive. The other three databases collect forms related to the tracking of antitoxin release and patient monitoring under an IRB (Institutional Review Board)-approved IND (Investigational New Drug) protocol. The database known as "Botulism.mdb" is used for forms 1 and 2 under the IND; this database contains PII and is in a secured folder on the EDEB National Surveillance share drive. Two tables within Botulism.mdb are stored on a SQL server (BOT\_EOCLINELIST) and accessed through the Microsoft Access frontend. The database known as "HBAT2.mdb" is used for patient clinical symptom tracking and antitoxin accountability; this database contains PII, is linked to Botulism.mdb by a single variable and is in a secured folder on the EDEB National Surveillance share drive.

\*13. Indicate if the system is new or an existing one being modified:

New

\*17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?

TIP: If the answer to Question 17 is "No" (indicating the system does not contain PII), only the remaining PIA Summary tab questions need to be completed and submitted. If the system does contain PII, the full PIA must be completed and submitted. (Although note that "Employee systems," i.e., systems that collect PII "permitting the physical or online contacting of a specific individual ... employed [by] the Federal Government - only need to complete the PIA Summary tab.)

Yes

17a. Is this a GSS PIA included for C&A purposes only, with no ownership of underlying application data? If the response to Q. 17a is Yes, the response to Q. 17 should be No and only the PIA Summary must be completed. NOTE: TO BE DETERMINED AND COMPLETED BY OCISO ONLY!!!

\*19. Are records on the system retrieved by 1 or more PII data elements?

Yes

\*21. Is the system subject to the Privacy Act? (If the response to Q. 19 is Yes, the response to Q. 21 must be Yes and a SORN number is required for Q. 4)

Yes

\*23. If the system shares or discloses PII, please specify with whom and for what purpose(s):

Yes, only with other divisions within this agency:  
Division of Global Migration and Quarantine (DGMQ), Regulatory Affairs (OD, NCEZID), Drug Services (Division of Scientific Resources) for patient follow up to ensure all required IRB forms are completed, and with officials from Drug Services (Division of Scientific Resources) to ensure delivery of antitoxin to the correct person.

\*30. Please describe in detail: (1) The information the agency will collect, maintain, or disseminate (clearly state if the information contained in the system ONLY represents federal contact data); (2) Why and for what purpose the agency will use the information; (3) Explicitly indicate whether the information contains PII; and (4) Whether submission of personal information is voluntary or mandatory:

1. A list of all confirmed botulism cases in the United States and tracking of antitoxin release and patient monitoring under an IRB (Institutional Review Board)-approved IND (Investigational New Drug) protocol for the botulism antitoxin
2. These data are used to monitor trends in disease occurrence, describe the epidemiology of botulism in the United States, as a resource during cluster investigations, and to monitor the release and administration of botulism antitoxin.
3. The information does contain PII
4. Submission of personal information is mandatory



PIA SUMMARY

1

The following required questions with an asterisk (\*) represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget (OMB) and public posting in accordance with OMB Memorandum (M) 03-22.

Note: If a question or its response is not applicable, please answer "N/A" to that question where possible. If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of personally identifiable information (PII). If no PII is contained in the system, please answer questions in the PIA Summary Tab and then promote the PIA to the Senior Official for Privacy who will authorize the PIA. If this system contains PII, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.

2

Summary of PIA Required Questions

\*Is this a new PIA?

No

If this is an existing PIA, please provide a reason for revision:

Annual Review

\*1. Date of this Submission:

October 30, 2012

\*2. OPDIV Name:

CDC/OID/NCEZID

3. Unique Project Identifier (UPI) Number for current fiscal year:

009-20-01-05-02-2045-00

\*4. Privacy Act System of Records Notice (SORN) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):

N/A

\*5. OMB Information Collection Approval Number:

N/A

\*6. Other Identifying Number(s):

\*7. System Name (Align with system item name):

Laboratory Based Enteric Disease Surveillance (LEDS)

\*9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:

Point of Contact Information

POC Name

Kathleen Fullerton

\*10. Provide an overview of the system:

Note: If SSN's (Social Security Numbers) will be collected, maintained (stored), disseminated and/or pass through within any database(s), record(s), file(s) or website(s) hosted by this system you must complete and submit **Attachment A – SSN Elimination or Usage Approval Request** located at <http://intranet.cdc.gov/ociso/pandp/policy.html>

According to OMB 07-16M, All agencies MUST participate in government-wide effort to eliminate unnecessary use of and explore alternatives to agency use of Social Security Numbers as a personal identifier for both Federal employees and in Federal programs.

LEDS is a CDC-developed application to capture surveillance data about laboratory specimens. Data from this system is used for disease monitoring and analysis at CDC. The

old system was a DOS-based standalone application distributed to all State Public Health Laboratories. The LEDS system will replace the old DOS system. During the design phase of the LEDS, it was determined that states no longer needed all the functionality provided by the old DOS system so the functionality was narrowed down to a secure mechanism for transporting data from Public Health Sites to CDC.

LEDS is a combination of procedures and applications for transmitting laboratory surveillance data from external sites to CDC. External sites are given disease specific instructions to develop an ASCII delimited file from their Laboratory Information Management System (LIMS). This file is transported through Public Health Information Network Messaging System (PHINMS) to CDC. Once the data is received at CDC, a CDC developed ASP tool validates file contents, stores errors in an error log, copies the file and some of the manifest components to a disease specific working database and then copies the same information to an ASCII file that is stored for archival and validation purposes. The CDC tool is scheduled to run at regular intervals and is customized and stored separately for each disease program. The disease specific database is used by programs for disease monitoring and statistical analysis.

External sites are typically Public Health Laboratories or organizations that collect public health information. External Sites manage their own PHINMS installation and are walked thru the setup by a PHINMS Helpdesk at CDC.

\*13. Indicate if the system is new or an existing one being modified:

Existing

\*17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?

TIP: If the answer to Question 17 is "No" (indicating the system does not contain PII), only the remaining PIA Summary tab questions need to be completed and submitted. If the system does contain PII, the full PIA must be completed and submitted. (Although note that "Employee systems," - i.e., systems that collect PII "permitting the physical or online contacting of a specific individual ... employed [by] the Federal Government - only need to complete the PIA Summary tab.)

Yes

17a. Is this a GSS PIA included for C&A purposes only, with no ownership of underlying application data? If the response to Q. 17a is Yes, the response to Q. 17 should be No and only the PIA Summary must be completed. TO BE DETERMINED AND COMPLETED BY OCISO ONLY!!!

\*19. Are records on the system retrieved by 1 or more PII data elements?

No. Once the records are stored in the database, records are retrieved based upon year, pathogen or reporting site.

\*21. Is the system subject to the Privacy Act? (If the response to Q. 19 is Yes, the response to Q. 21 must be Yes and a SORN number is required for Q. 4)

No

\*23. If the system shares or discloses PII, please specify with whom and for what purpose(s):

No PII data is shared or disclosed. Data is used internally and only by the program collecting the data.

\*30. Please describe in detail: (1) The information the agency will collect, maintain, or disseminate (clearly state if the information contained in the system ONLY represents federal contact data); (2) Why and for what purpose the agency will use the information; (3) Explicitly indicate whether the information

contains PII; and (4) Whether submission of personal information is voluntary or mandatory:

The purpose of the system is to conduct National Surveillance on specific Foodborne pathogens. This information is collected from State Health Laboratories and Epi Offices. Detailed isolate information is collected along with minimal demographic information such as State, County, Sex and Age. Once or twice a year, case studies are conducted and the interview questions are transmitted and added to the database. No PII data is collected for case studies. The data is stored in a SQL table and only designated program personnel have access to it. The data is used to report national trends, outbreak detection and to guide and promote CDC's programs in reducing Foodborne illness. Some of the pathogens are on the nationally notifiable list, but personal information submission is deemed voluntary.

*\*31. Please describe in detail any processes in place to: (1) Notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) Notify and obtain consent from individuals regarding what PII is being collected from them; and (3) How the information will be used or shared. (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]):*

All information is obtained at the State Health Department level. CDC does not interact with any individual and therefore all responsibility for patient notification resides with the State.

*\*32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII)*

No

*\*37. Does the website have any information or pages directed at children under the age of thirteen?*

No

*\*50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN)*

Follows CDC and HHS records retention and management policy

*\*54. Briefly describe in detail how the PII will be secured on the system using administrative, technical, and physical controls:*

Any potential PII data is securely encrypted and transmitted via the CDC approved PHINMS program. Once received, the data is extracted and stored in a secure SQL table. Access to the table is controlled by the program using CDC approved methods. Only CDC authorized staff who are given explicit rights to the table can access it.

**APPROVAL/DEMOTION**

**1 System Information**

System Name: \_\_\_\_\_

**2 PIA Reviewer Approval/Promotion or Demotion**

Promotion/Demotion: \_\_\_\_\_

Comments: \_\_\_\_\_

Approval/Demotion Point of Contact: \_\_\_\_\_

Date: \_\_\_\_\_

**3 Senior Official for Privacy Approval/Promotion or Demotion**

Promotion/Demotion: \_\_\_\_\_

Comments: \_\_\_\_\_

**4 OPDIV Senior Official for Privacy or Designee Approval**

Please print the PIA and obtain the endorsement of the reviewing official below. Once the signature has been collected, retain a hard copy for the OPDIV's records. Submitting the PIA will indicate the reviewing official has endorsed it

This PIA has been reviewed and endorsed by the OPDIV Senior Official for Privacy or Designee (Name and Date):

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Name:	_____
Date:	_____

**5 Department Approval to Publish to the Web**

Approved for web publishing \_\_\_\_\_

Date Published: \_\_\_\_\_

Publicly posted PIA URL or no PIA URL explanation: \_\_\_\_\_