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Privacy Impact Assessment Form v 1.45 Status Draft F-20292 1/27/2015 7:25:07 AM Form Number Form Date Question Answer OPDIV: CDC PIA Unique Identifier: P-3096596-687484 2a Name: Laboratory Based Enteric Disease Surveillance (LEDS) General Support System (GSS) Major Application Minor Application (stand-alone) The subject of this PIA is which of the following? Minor Application (child) C Electronic Information Collection ○ Unknown Identify the Enterprise Performance Lifecycle Phase 3a Operations and Maintenance of the system. ○ Yes 3b Is this a FISMA-Reportable system? No Does the system include a Website or online application available to and for the use of the general No public? Agency Identify the operator. Contractor **POC Title Business Steward POC Name** Patti Griffin POC Organization | CDC/OID/NCEZID Point of Contact (POC): **POC Email** pmg1@cdc.gov **POC Phone** 404.639.3384 New Is this a new or existing system? Existing Does the system have Security Authorization (SA)? No February 19, 2015 8b Planned Date of Security Authorization ☐ Not Applicable

11 Describe the purpose of the system.

LEDS is a combination of CDC-developed message handlers and SAS programs that capture, store and analyze laboratory confirmed isolate information obtained through the transmittal and receiving of isolate information from external laboratories. Data from this system is used by CDC for disease surveillance and analysis. There are four programs that participate and receive some or all of their data via this system: Foodborne, Influenza, Rabies and FoodNet.

Four independent programs fall under the umbrella that is called LEDS. Each program collects the same basic demographic information and differentiates themselves by the additional information each collects. The external sites are provided detailed instructions on how to create the disease specific ASCII delimited files from their Laboratory Information Management System (LIMS). They send these files via CDC's Public Health Information Network Messaging System (PHINMS).

The information collection and analysis requirements of the LEDS programs are managed independently through their corresponding CDC divisions as follows:

Division of Foodborne, Waterborne and Environmental Diseases (NCEZID\DFWED)

- Foodborne
 - o Diseases: Campylobacteriosis, Escherichia coli, Salmonellosis, Shigellosis
 - o Detailed isolate information is collected along with minimal demographic information such as State, Zip code, County, Sex, Ethnicity, Race and Age.

Describe the type of information the system will collect, maintain (store), or share. (Subsequent questions will identify if this information is PII and ask about the specific data elements.)

FoodNet

- o Diseases: Campylobacteriosis, Cholera, Cryptosporidiosis, Cyclosporiasis, Escherichia coli, HUS, Listeriosis, Salmonellosis, Shigellosis, Yersiniosis
- o Detailed isolate information is collected along with minimal demographic information such as State, Zip code, County, Sex, Ethnicity, Race 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.

Influenza Division (NCIRD/ID)

- Influenza
 - o Diseases: Influenza
 - o Detailed isolate information is collected along with minimal demographic information such as State, Zip code, County, Sex, Ethnicity, Race and Age.

Division of High-Consequence Pathogens and Pathology (NCEZID\DHCPP)

- Rabies
 - o Diseases: Rabies
 - o Detailed isolate information is collected along with minimal demographic information such as State, Zip code, County, Sex, Ethnicity, Race and Age.

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13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	LEDS is a combination of CDC-developed message handlers and SAS programs that capture, store and analyze laboratory confirmed isolate information obtained through the transmittal and receiving of isolate information from external laboratories. Data from this system is used by CDC for disease surveillance and analysis. There are four programs that participate and receive some or all of their data via this system: Foodborne, Influenza, Rabies and FoodNet. Detailed isolate information is collected along with minimal demographic information such as State, Zip code, County, Sex, Ethnicity, Race and Age.		
1./	Does the system collect maintain use or share DII2	© Ye	25	,
14	Does the system collect, maintain, use or share PII?	○ No)	
		Social Security Number	□ Date of Birth	
		☐ Name	Photographic Identifiers	
		Driver's License Number	☐ Biometric Identifiers	
		☐ Mother's Maiden Name	☐ Vehicle Identifiers	
		E-Mail Address		
		Phone Numbers	Medical Records Number	
	Indicate the type of PII that the system will collect or	☐ Medical Notes	Financial Account Info	
15	maintain.	Certificates	Legal Documents	
		☐ Education Records	Device Identifiers	
		☐ Military Status	☐ Employment Status	
		Foreign Activities	Passport Number	
		☐ Taxpayer ID	Ethnicity	
		Race	County	
		Gender	Zip code	
		Employees		
		Public Citizens		
	Indicate the categories of individuals about whom PII	Business Partners/Contacts (Federal, state, local agencies)		
16	Indicate the categories of individuals about whom PII is collected, maintained or shared.	☐ Vendors/Suppliers/Contractors		
		□ Patients		
		Other		
17	How many individuals' PII is in the system?	1,000,000 or more		
18	For what primary purpose is the PII used?	The PII is used by programs for disease surveillance and statistical analysis.		
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	n/a		
20	Describe the function of the SSN.	n/a		

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20a	Cite the legal authority to use the SSN.	n/a		
21	Identify legal authorities governing information use and disclosure specific to the system and program.	Public Health Service Act, Section 306(b) (42 U.S.C. 242k)		
22	Are records on the system retrieved by one or more PII data elements?	○ Yes		
22a	Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or identify if a SORN is being	Published: Published: Published: In Progress		
23	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains		
23a	Identify the OMB information collection approval number and expiration date.	Not-Applicable		
24	Is the PII shared with other organizations?	○ Yes		
		☐ Within HHS		

Other Federal Agency/Agencies

State or Local
Agency/Agencies

☐ Private Sector

Identify with whom the PII is shared or disclosed and for what purpose.

24b	Describe any agreements in place that authorizes the information sharing or disclosure (e.g. Computer Matching Agreement, Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	
24c	Describe the procedures for accounting for disclosures	
25	Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.	No prior notice is given. 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.
26	Is the submission of PII by individuals voluntary or	Voluntary
	mandatory?	
27	Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.	No option exists. 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. The LEDS system receives data after patient has voluntarily shared Data with the state Department of Health with the express knowledge that such data may be shared with other relevant entities/organizations.
28	Describe the process to 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 original collection). Alternatively, describe why they cannot be notified or have their consent obtained.	State health department has the notification responsibilities as they are the collectors and originators of the data. Changes are received into LEDS System secondarily.
29	Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.	The Security Steward and Information System Security Officer (ISSO) are notified and analyze the incident. If the incident proves that PII was disclosed, CSIRT and the CPO are notified within one hour. At CDC's direction, the corresponding State health departments will be engaged to notify affected individuals since they are the collectors/originators of the data.
30	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. If no processes are in place, explain why not.	OCISO requires annual security control assessment of the systems confidentiality, integrity, and availability. In addition, data cleaning and error reporting routines run on every State Health Laboratory record received to ensure the data's accuracy and relevance. At the end of each calendar year, final reviews and corrections (if necessary) are conducted before the calendar year data file is finally "Closed Out" and made available for analysis and publication by the program in papers and journals.

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		Users		
	dentify who will have access to the PII in the system and the reason why they require access.		Full Access to properly manage data	
		□ Developers	Read/Write Access in order to help maintain data and its accuracy	
		Contractors		
		○ Others	SME; Read Access Level to help interpret meaning of data	
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Role-based Access Co	ontrol (RBAC)	
33	Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.	The Least Privilege m	nodel is used	
34	Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.	Annual CDC Security and Privacy Awareness Training (SAT)		
35		Role-based Training to use the database is given to individuals with access priviledges.		
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	YesNo		
37	regard to the retention and destruction of PII. Cite specific records retention schedules.	Final reports and substantive reporting materials are maintained permanently (CDC RCS, B-321, 4). Other input/output records and system data that may be required for follow-up are disposed of after 10 years. Disposal methods include erasing computer tapes, burning or shredding paper materials or transferring records to the Federal Records Center when no longer needed for evaluation and analysis. In addition, electronic media is subject to ITSO zero-wipe pass methodology.		
38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	Operational Controls include physical facilities management policies, data center and media protection procedures, security & privacy incident response procedures; and mandatory annual security & privacy awareness training; and Technical Controls include application level role based access controls; servers audit and accountability requirements; encryption of PII at rest and in transit; and adherence to organizationally defined minimum security controls.		
RE	VIEWER QUESTIONS: The following section contains Re Seni	eviewer Questions whor Officer for Privacy.	nich are not to be filled out unless the user i	s an OPDIV
	Reviewer (Questions	Answer	

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	Reviewer Questions	Answer
1	Are the questions on the PIA answered correctly, accurately, and completely?	○ Yes ○ No
Reviewer		UNO .
Notes		∩Yes
	Does the PIA appropriately communicate the purpose of PII in the system and is the purpose justified by appropriate legal authorities?	○ No
Reviewer Notes		
	Do system owners demonstrate appropriate understanding of the impact of the PII in the system and provide sufficient oversight to employees and contractors?	○Yes
	system and provide sufficient oversight to employees and contractors:	○ No
Reviewer Notes		
4	Does the PIA appropriately describe the PII quality and integrity of the data?	○ Yes
7	boes the FIX appropriately describe the Fit quality and integrity of the data:	○ No
Reviewer Notes		
5	Is this a candidate for PII minimization?	○ Yes
,	is this a cardidate for thirminization:	○ No
Reviewer Notes		
6	Does the PIA accurately identify data retention procedures and records retention schedules?	○Yes
	boes the first condition for t	○ No
Reviewer Notes		
7	Are the individuals whose PII is in the system provided appropriate participation?	○ Yes
,	Are the manuals whose i in sin the system provided appropriate participation:	○ No
Reviewer Notes		
8	Does the PIA raise any concerns about the security of the PII?	○ Yes
<u> </u>	boes the First unit concerns about the security of the Fir.	○ No
Reviewer Notes		
u	Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?	○ Yes
Reviewer		○No
Notes		
10	Is the PII appropriately limited for use internally and with third parties?	○ Yes
	The state of the s	○No
Reviewer Notes		
11	Does the PIA demonstrate compliance with all Web privacy requirements?	○ Yes
		○ No

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Reviewer Questions				Answer	
Reviewer Notes					
12 Were any changes made to the system because of the completion of this PIA?				○ Yes	
		,			○ No
Reviewer Notes					
G eneral Comm	General Comments				
OPDIV Senior (for Privacy Sig			HHS Senior Agency Official for Privacy		
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