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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date 07/23/18

	Question	Answer
1	OPDIV:	CDC
2	PIA Unique Identifier:	0920-18CI
2a	Name:	Evaluation of TransLife Center (TLC): A Locally-Developed Comb
3	The subject of this PIA is which of the following?	○ General Support System (GSS) ○ Major Application ○ Minor Application (stand-alone) ○ Minor Application (child) ◉ Electronic Information Collection ○ Unknown
3a	Identify the Enterprise Performance Lifecycle Phase of the system.	Initiation
3b	Is this a FISMA-Reportable system?	○ Yes ◉ No
4	Does the system include a Website or online application available to and for the use of the general public?	○ Yes ◉ No
5	Identify the operator.	◉ Agency ○ Contractor
6	Point of Contact (POC):	POC Title: Project Officer POC Name: Denson, Damian POC Organization: NCHHSTP/DHPIRS/PRB POC Email: dvd5@cdc.gov POC Phone: 404.639.6125
7	Is this a new or existing system?	◉ New ○ Existing
8	Does the system have Security Authorization (SA)?	○ Yes ◉ No
8b	Planned Date of Security Authorization	☒ Not Applicable

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8c	Briefly explain why security authorization is not required	TBD
10	Describe in further detail any changes to the system that have occurred since the last PIA.	N/A
11	Describe the purpose of the system.	The purpose of this study is to evaluate a locally developed and potentially effective intervention, TransLife Center (TLC), which provides combination (biomedical, behavioral, and social/ structural) HIV prevention services to adult transgender women at high risk for HIV infection. The information collected through this study is used to evaluate whether exposure to TLC prevention services results in improvements in participants' self-reported sexual health and HIV prevention behaviors, beliefs and attitudes. The study will use a pre-post design to compare pre-intervention (baseline) levels of HIV risk to those at four and eight months post baseline.
12	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.)	The TransLife Center (TLC) study collects: Names, Phone Numbers, Email, Mailing Address, Date of Birth (DOB), Facebook ID, and Medical Notes. Data collected through the study will be used to evaluate a locally developed HIV prevention intervention for transgender women. The Chicago House & Social Service (CHSS) Agency, Ann & Robert H. Lurie Children's Hospital of Chicago, and the University of Illinois at Chicago collect the information for this study. The PII collected is not transmitted or stored with any other information nor is it transmitted CDC. The PII is alway kept separate from study data and never linked to the CDC data. All collected data is de-identified prior to transmission to CDC.
13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	The TransLife Center (TLC) provides a combination of HIV prevention services to adult transgender women at high risk for HIV infection. Participation is voluntary and confidential. Participants who are eligible and interested in the study will be enrolled following consent. Written consents are stored in a locked cabinet away from workstations and only accessed in the event of a study visit, consent amendment, or an audit. Data files maintained in de-identified format are not linked to individual names or identifiers, and are stored in password-protected files on secure servers. This database is used to schedule and track study visits and accessible only to study staff investigators and data manager who have access to this data. This data is completely password protected. HIV/STI testing is completed by clinical staff of Heartland Health Outreach (HHO) or by non-research staff of Chicago House, who are under contract from Chicago Dept. of Public Health, (CDPH). Coded and encrypted electronic data files collected include, program attendance records, HIV/STI screening results, and Pre-exposure prophylaxis (PrEP), and, survey, biomarker results, and medical visit information are transferred from Chicago House to Lurie Children's Hospital, from Lurie's Children Hospital to University of Chicago for analysis in a secure database. All biological specimens will be labeled with coded identifiers for processing to maintain privacy All identifying information will be destroyed at the end of study.

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14	Does the system collect, maintain, use or share **PII**?	(•) Yes ( ) No
15	Indicate the type of PII that the system will collect or maintain.	[ ] Social Security Number; [x] Date of Birth; [x] Name; [ ] Photographic Identifiers; [ ] Driver's License Number; [ ] Biometric Identifiers; [ ] Mother's Maiden Name; [ ] Vehicle Identifiers; [x] E-Mail Address; [x] Mailing Address; [x] Phone Numbers; [ ] Medical Records Number; [x] Medical Notes; [ ] Financial Account Info; [ ] Certificates; [ ] Legal Documents; [ ] Education Records; [ ] Device Identifiers; [ ] Military Status; [ ] Employment Status; [ ] Foreign Activities; [ ] Passport Number; [ ] Taxpayer ID; Name, phone number, Email, DOB, Medical Notes, Mailing address, and Social Media Information collected are not included in the CDC data sets.; Other...; Other...; Other...; Other...
16	Indicate the categories of individuals about whom PII is collected, maintained or shared.	[ ] Employees; [x] Public Citizens; [ ] Business Partners/Contacts (Federal, state, local agencies); [ ] Vendors/Suppliers/Contractors; [ ] Patients; Other
17	How many individuals' PII is in the system?	100-499
18	For what primary purpose is the PII used?	The primary purpose of the PII is to maintain and track the participants throughout the study.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	Secondary use of PII is for analysis.
20	Describe the function of the SSN.	N/A
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, Title III, Section 301
22	Are records on the system retrieved by one or more PII data elements?	(•) Yes ( ) No

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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 developed.	Published:	Privacy Act System Notice 09-20-0136: "Epidemio
		Published:	
		Published:	
		☐ In Progress	
23	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains	
		☒ In-Person	
		☐ Hard Copy: Mail/Fax	
		☐ Email	
		☐ Online	
		☒ Other	
		Government Sources	
		☐ Within the OPDIV	
		☐ Other HHS OPDIV	
		☐ State/Local/Tribal	
		☐ Foreign	
		☐ Other Federal Entities	
		☐ Other	
		Non-Government Sources	
		☒ Members of the Public	
		☐ Commercial Data Broker	
		☐ Public Media/Internet	
		☐ Private Sector	
		☐ Other	
23a	Identify the OMB information collection approval number and expiration date.	New ICR	
24	Is the PII shared with other organizations?	○ Yes ◉ No	
24a	Identify with whom the PII is shared or disclosed and for what purpose.	☐ Within HHS ☐ Other Federal Agency/Agencies ☐ State or Local Agency/Agencies ☐ Private Sector	
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)).	There are no MOUs or ISA s for this information collection activity, as those accessing the data are joint awardees of the funding. The HHO is the ongoing medial provider of the TLC and is not receiving any study data.	
24c	Describe the procedures for accounting for disclosures	None	

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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.	Participants will be notified in writing in the consent form during the consent process that their personal information will be collected. The consent process which is a discussion between the participant and the study staff notifies individuals that their PII will be collected.
26	Is the submission of PII by individuals voluntary or mandatory?	(•) 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.	Participants may opt out of the information collection during either the screening or consent processes. Participants who are eligible and interested in participation will be enrolled and consent obtained during either the screening or consent processes.
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.	Participants may be notified in writing by study staff if major changes occur to the system.
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.	Participants will be provided contact information and instruction to contact either the grantee principal investigators as well as the compliance officer for the Lurie Children's Hospital Institutional Review Board (IRB).
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.	Data quality will be monitored regularly by the Lurie Children's PI and data manager. This will include review of study files and data for accuracy (Quality Assurance), reconciliation of any file and data problems as soon as possible, and cleaning of study data and creation of a codebook prior to analysis. No PII is transmitted to CDC, all collected data will be De-Identified prior to transmission. The Chicago House & Social Service Agency, and Lurie Children's Hospital keep all PII data and never linked to the CDC data.
31	Identify who will have access to the PII in the system and the reason why they require access.	☐ Users ☐ Administrators ☐ Developers ☐ Contractors ☒ Others — Chicago House & Social Service Agency, Lurie Children's, and the
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	The CDC study team have defined that roles and responsibilities to access PII is limited to only study investigators (Co-PIs, Program Director, and Program Manager) will have access to recruitment/retention, survey and interview data. The study data manager has a defined role that will only have access to survey and interview data.

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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.	Access to sensitive Personally Identifiable Information (PII) will be restricted to individuals trained in human subject protections who are listed on the Institutional Review Board (IRB) protocol. All PII is collected for a specific and identifiable purpose with access restricted to specific job tasks and individuals who perform those tasks. Access to PII in study data collected for the purposes of analysis is limited to the study investigators and data manager.
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.	The grantee Co-PIs, Program Director and Program Manager have completed the web-based course, "Protecting Human Research Participants" provided by the NIH Office of Extramural Research. The Program Director and Program Manager have also completed a 4-hour training session on conducting consent, protecting confidentiality and privacy, data collection, and secure storage provided by one of the study Co-PIs.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	System users also receive training related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	○ Yes ◉ No
37	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific records retention schedules.	Records are retained and disposed of in accordance with the CDC Records Control Schedule 04-4-22 Family of HIV Surveys, Division of HIV/AIDS Prevention/Surveillance and Epidemiology, (N1-442-02-3-4, Item 1). Record copy of study reports are maintained in agency records from two to three years in accordance with retention schedules. Source documents for computer are disposed of when no longer needed by program officials. Personal identifiers may be deleted from records when no longer needed in the study as determined by the system manager, and as provided in the signed consent form, as appropriate. Disposal methods include erasing computer disks or tapes, burning or shredding paper materials or transferring records to the Federal Records Center when no longer needed for evaluation and analysis. Cut off closed grant, contract, or cooperative agreement files at the end of the calendar year in which the project ends or a final report is written and destroy six years after cut off. All identifying information will be destroyed as soon as possible at the end of study and no longer than three years from the closure of the study protocol with the Lurie Children's Hospital IRB.

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38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	Physical Consents and locator forms will be stored in locked cabinets in the research offices. Data files (survey and interview) maintained in De-Identified format, stored in password-protected files on secure servers. All biological specimens labeled with coded identifiers for processing to maintain confidentiality. Biological specimens (urine, anal swabs, blood) for HIV/STI testing will be de-identified, coded and transferred by local courier for processing in external laboratories used commonly in the testing programs at Lurie Children's and Chicago House. Technical Tracking files (i.e., linking database) are maintained in a highly secure scheduling and monitoring database at Northwestern University. This database is used to schedule and track study visits and accessible only to study staff; it is completely password protected. Survey data employs Transport Layer Security (TLS) Encryption during transmission. Administrative Lurie Children's and Chicago House are responsible for following their organizations specific security procedures, which at a minimum include restricting access to the PII to only authorized users. The grantee Co-PIs, Program Director and Program Manager have completed the web-based course, "Protecting Human Research Participants."

REVIEWER QUESTIONS: The following section contains Reviewer Questions which are not to be filled out unless the user is an OPDIV Senior Officer for Privacy.

	Reviewer Questions	Answer
1	Are the questions on the PIA answered correctly, accurately, and completely?	◯ Yes ◯ No
Reviewer Notes		
2	Does the PIA appropriately communicate the purpose of PII in the system and is the purpose justified by appropriate legal authorities?	◯ Yes ◯ No
Reviewer Notes		
3	Do system owners demonstrate appropriate understanding of the impact of the PII in the system and provide sufficient oversight to employees and contractors?	◯ Yes ◯ No
Reviewer Notes		
4	Does the PIA appropriately describe the PII quality and integrity of the data?	◯ Yes ◯ No
Reviewer Notes		
5	Is this a candidate for PII minimization?	◯ Yes ◯ No

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	Reviewer Questions	Answer
Reviewer Notes		
6	Does the PIA accurately identify data retention procedures and records retention schedules?	◯ Yes ◯ No
Reviewer Notes		
7	Are the individuals whose PII is in the system provided appropriate participation?	◯ Yes ◯ No
Reviewer Notes		
8	Does the PIA raise any concerns about the security of the PII?	◯ Yes ◯ No
Reviewer Notes		
9	Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?	◯ Yes ◯ No
Reviewer Notes		
10	Is the PII appropriately limited for use internally and with third parties?	◯ Yes ◯ No
Reviewer Notes		
11	Does the PIA demonstrate compliance with all Web privacy requirements?	◯ Yes ◯ No
Reviewer Notes		
12	Were any changes made to the system because of the completion of this PIA?	◯ Yes ◯ No
Reviewer Notes		

General Comments	

OPDIV Senior Official for Privacy Signature	Beverly E. Walker -S Digitally signed by Beverly E. Walker -S Date: 2018.07.30 18:10:58 -04'00'	HHS Senior Agency Official for Privacy	