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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date

	Question	Answer
1	OPDIV:	CDC
2	PIA Unique Identifier:	0920-18AQQ
2a	Name:	HIV Prevention Among Latina Transgender Women Who Have S
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: Thomas Painter, PhD POC Organization: Division of HIV/AIDS Prevention (POC Email: tcp2@cdc.gov POC Phone: 404-639-6113
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

Save

8c	Briefly explain why security authorization is not required	Not applicable
10	Describe in further detail any changes to the system that have occurred since the last PIA.	Not applicable
11	Describe the purpose of the system.	The purpose of the system is to evaluate the efficacy of ChiCAS (Chicas Creando Acceso a la Salud [Chicas: Girls Creating Access to Health]), a two-session Spanish language intervention that provides human immunodeficiency virus (HIV) prevention services to Hispanic/Latina adult transgender women who have sex with men.
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 type of information the system will collect, maintain, and share includes name, Email address, phone numbers, Facebook name/alias, gender identity, race/ethnicity, employment status, mailing address, contact information for two personal contacts, sex at birth, age, education history, country of origin, and number of years of United States (US) residency. The system will also collect information on participant identifications (IDs), participants' experienced barriers to accessing health care, results of their most recent HIV test, use of hormone therapy and location and contact information for the prescribing physician and supplying pharmacy, knowledge about HIV, other sexually transmitted diseases and pre-exposure prophylaxis (PrEP), their sexual experiences and drug and alcohol use, and their social support systems in the US, and consistent condom use and the use of PrEP and medically supervised hormone therapy, participant attendance at intervention sessions, and digital recordings of interviews.
13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	Any and all contact information will be collected, maintained, and/or shared to facilitate contacting study participants during the course of the study as well as to administer interviews and follow-up assessments. Contact information of participants' friends and family will be used should participants become difficult to find. All data will be collected, maintained, and shared in order to analyze and examine participant exposure to the intervention during its implementation. Participant's digital recordings of interviews will be maintained temporarily until transcribed. Once transcribed, digital recordings are destroyed.
14	Does the system collect, maintain, use or share **PII**?	(•) Yes ( ) No

Save

15	Indicate the type of PII that the system will collect or maintain.	☐ Social Security Number ☐ Date of Birth ☒ Name ☐ Photographic Identifiers ☐ Driver's License Number ☐ Biometric Identifiers ☐ Mother's Maiden Name ☐ Vehicle Identifiers ☒ E-Mail Address ☒ Mailing Address ☒ Phone Numbers ☐ Medical Records Number ☐ Medical Notes ☐ Financial Account Info ☐ Certificates ☐ Legal Documents ☐ Education Records ☐ Device Identifiers ☐ Military Status ☒ Employment Status ☐ Foreign Activities ☐ Passport Number ☐ Taxpayer ID Facebook name/alias Race/ethnicity Age Sex at birth Country of origin
16	Indicate the categories of individuals about whom PII is collected, maintained or shared.	☐ Employees ☒ 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 using PII is to facilitate contacting study participants during the course of the study as well as to administer interviews and follow-up assessments.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	The secondary use of PII is to describe the socio-demographic characteristics of study participants (e.g., gender identity, race/ethnicity, etc.).
20	Describe the function of the SSN.	Not Applicable
20a	Cite the **legal authority** to use the SSN.	Not Applicable
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

Save

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: 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.	TBD
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)).	
24c	Describe the procedures for accounting for disclosures	

Save

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.	Potential study participants will receive a consent form as part of an informed consent process. Grantees also will describe data types that will be collected to participants before study activities begin. All information collection and maintenance will be done by grantees; Centers for Disease Control and Prevention (CDC) project staff will neither interact with study participants nor participate in the collection of participants' information.
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.	Grantees will explain that participants have the right to decline participation at the time of consent and at any time during any study activity.
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.	Grantees will explain to participants that it is the grantees who will be in possession of participants' contact information, and that they will contact participants in the event of major changes to the system and/or use of participant's PII. Should major system changes actually occur, an Institutional Review Board (IRB) amendment will be drafted and a determination made about whether the system changes necessitate (1) updating the consent form and/or (2) contacting participants to update them about protocol changes.
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.	Grantees will explain to participants during the informed consent process ways participants can raise any concerns about the handling of their PII at any time during the study. Individuals concerned about breaches in confidentiality or misuse of PII may contact the Wake Forest School of Medicine or the Chairman of the IRB. These individuals' phone numbers are provided to participants during the informed consent process. After being informed of study-related privacy issues, the institutional chief privacy officer charges a team of staff to investigate privacy-related issues. This investigation includes interviews with the PI, study team, and research participant/ complainant; and review of all study procedures, consent procedures, and deviations. Subsequently, the chief privacy officer writes a report that is filed with the grantee and meets with the study team to review the report. The team in turn adheres to the recommended actions.

Save

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.	Integrity: Data access will be limited strictly to grantees based on secure storage procedures for all paper forms and electronic files handling. Accuracy: Each paper assessment questionnaire is scanned and immediately validated by comparing the scanned document to the original questionnaire to ensure no mistakes or errors are made during the scanning process. Once validated, the dataset will be non-editable. Transcripts of all digital recordings will be compared to the recordings to ensure no mistakes or errors occurred. Corrections will be made as needed. Once validated, the dataset will be non-editable. Availability: PII, datasets, and transcripts will be maintained by grantees. CDC will receive a copy of de-identified aggregate study data at the end of the study, and we will make the aggregate data available for potential analysis by third parties based on conditions specified in a data sharing agreement. Relevancy: CDC will collaborate with grantees to identify variables and measures needed for the study, thereby avoiding the collection of data that are not relevant to study objectives.
31	Identify who will have access to the PII in the system and the reason why they require access.	☐ Users ☒ Administrators: Grantees ☐ Developers ☐ Contractors ☐ Others
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Elements of PII in the system are accessible only by grantee administrators with authorized credentials.
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.	Separate locked cabinets will house paper forms with PII. The hard-copy-only document linking PII to datasets is stored and locked separately from all other data, accessible by one senior administrator authorized to handle and view it.
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.	Before any data are collected, grantees will be trained in IRB, informed consent procedures, conducting the rapid INSTI test, and collecting sensitive health data. Also, all study staff conducting human subjects research are required to complete an online certification every three years.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	Grantees will receive supplemental training on collecting data on issues specific to transgender persons. Team members also will attend agency-specific human subjects and client confidentiality trainings.
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	○ Yes ◉ No

Save

37	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific records retention schedules.	Study records containing PII will be destroyed no later than three years following the closure of the study in accordance with the study protocol.
38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	Administrative: Assessment data cannot be accessed based on PII, and access to study data will be limited to key grantees. Public access to de-identified study data after completion of the study and the reporting of study results will be determined by a study data sharing and data use agreement. Technical: Digital recordings of interviews will be destroyed by erasing after the recording transcriptions are verified. Completed assessments will be scanned, uploaded, and saved in a password-protected, secure network. No PII will be linked to participants' assessment data, and assessment data will be stored separately using randomly assigned, unique identification numbers for each participant. Only authorized study staff with credentials will be able to access study data housed electronically. Once logged into the system with credentials, the system will automatically logout a user if a period of inactivity occurs. Network servers are equipped with back-up servers, two firewalls, and encryption for added security. Physical: All systems are securely controlled in new state-of-the-art data center, which has limited access through badge access. PII portions of the system are paper-based and will not be stored electronically. Paper forms will be de-identified and uploaded and stored electronically. Only de-identified data will be stored in electronic format. Documents containing PII will be locked in a file cabinet, accessible only by authorized study staff. Records containing PII will be destroyed no later than three years after closure of the study in accordance with the study protocol.

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		

Save

	Reviewer Questions	Answer
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
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		

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OPDIV Senior Official for Privacy Signature	Jarell Oshodi -S Digitally signed by Jarell Oshodi -S Date: 2019.02.07 14:45:35 -05'00'	HHS Senior Agency Official for Privacy	