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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date 11/10/2021

	Question	Answer
1	OPDIV:	CDC/NCHHSTP/DHAP
2	PIA Unique Identifier:	0920-21HI
2a	Name:	Red Carpet Entry (RCE) Program Implementation
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: Behavioral Scientist POC Name: Deborah Gelaude POC Organization: CDC/NCHHSTP/DHAP POC Email: zoi1@cdc.gov POC Phone: 404-639-1905
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	CDC will only be receiving deidentified data.
10	Describe in further detail any changes to the system that have occurred since the last PIA.	New Information Collection.
11	Describe the purpose of the system.	The purpose of this information collection is to create a toolkit for HIV clinics to implement the Red Carpet Entry (RCE) Program and test the toolkit in two clinics. The study will evaluate the implementation of the RCE program utilizing the RCE toolkit, to ensure that: it can be easily used by clinic staff in engaging newly diagnosed persons with HIV (PWH) and persons returning to care into HIV medical care; that the program runs properly; and that PWH are connected to a provider or care team within 3 days. The study will evaluate key components that contribute to program effectiveness according to implementation science, including the implementation strategies used to prepare for and implement RCE, adaptations made to integrate RCE, implementation context, and implementation outcomes such as acceptability, appropriateness, feasibility, fidelity, reach, and sustainability. Based on the information collected in this study, the toolkit will be revised to include experiences of the clinics and their implementation strategies and adaptations. The RCE toolkit will be disseminated by CDC to the broader HIV health care community. This is important because only federal agencies like CDC have the resources and infrastructure to broadly disseminate evidence-based interventions (EBIs). Broad dissemination and uptake of EBIs like RCE can help lower population rates of HIV transmission.
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.)	PII will be abstracted from the Electronic Health Record (EHR) of clients enrolled in the Red Carpet Entry Program at participating study clinics. Participating clinics are subcontracted to implement RCE and collect data for this project. Staff participating in the RCE implementation at the participating clinics are located in local clinics and referred to as 'RCE clinic staff.' The Contractor will be responsible for collecting all data for this study. To ensure that respondents' health information is protected, we will take the following measures to separate PII from study-related data: (1) all respondents will receive unique identification codes, which will be stored separately from PII on a password protected computer and or locked file cabinet; data will be collected by trained RCE clinic staff using a secure, password-protected database stored on the participating clinic's secure server or project computer; (2) Contract study staff and RCE clinic staff who play a role in data collection and analysis will be trained in proper procedures for securing project data and protecting participant confidentiality; and (3) an encryption key will be used to transform dates included as part of the Electronic Health Record (EHR) records abstracted.

Save

13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	PII will be abstracted from the Electronic Health Record (EHR) of clients enrolled in RCE and collected from RCE clinic staff involved in implementing RCE via survey and interview data collection activities (data collection conducted by Contract study staff). Client PII is collected for the purpose of describing the sample and determining study outcomes (demographics, appointment dates, HIV diagnosis date, length of time from diagnosis to RCE visit). PII is collected from RCE clinic staff during the interview/survey for the purpose of describing the clinic staff sample (demographics). Additional PII is collected for purpose of implementing RCE, such as names and phone numbers/email addresses for contacting RCE clients when appointments are missed. Access to all PII is limited to clinic staff. PII accessed at participating clinics remains on site. PII from client data will not be transmitted to the Contractor or to the CDC. PII from participants will not be transmitted to CDC. PII that will be abstracted include; Name, email address, phone number, DOB, mailing address, sex, gender, race and ethnicity, appointment dates and clinic location.
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 ☒ 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 Race and Ethnicity Sex Appointment Dates Gender Clinic Location
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

Save

18	For what primary purpose is the PII used?	PII will be used to: follow up with participants related to medical visits missed; to describe the sample enrolled in the study; and to identify key research outcomes of the Red Carpet Entry Program implementation.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	Not applicable.
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, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)).Information use and disclosure is governed under Departmental regulations, 5 USC 301.
22	Are records on the system retrieved by one or more PII data elements?	○ Yes ◉ No
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

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.	Study participants will be provided information about the study, including data to be collected, during enrollment via the informed consent process. Information will be provided using an IRB approved consent form which will provide details about the study, data collection, procedures and how data and PII will be handled and stored. Clinic staff implementing RCE and participating as respondents will be informed about measures taken for data protection and confidentiality, and that data will be used in aggregate form only. RCE clients will be asked to consent to the access of their Electronic Health Record for visit and appointment dates, demographic data (race, ethnicity, age, gender), and date of HIV diagnosis. Participants will sign this form and will be offered a copy for their records.
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.	If individuals do not want to participate in the study after approached or consented, they can simply state so and they will not be consented or they will be removed from the study (respectively).
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.	The RCE clinic staff will explain to participants that it is the clinic 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.	RCE clinic staff 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 Contractor- Investigator in charge of the Study or the Local Institutional Review Board (IRB) of record via contact information provided in the informed consent document.

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 RCE clinic staff and Contract study staff based on secure storage procedures for all paper forms and electronic files handling. Availability: PII abstracted from EHRs will be strictly maintained by RCE clinic staff located in participating clinics and destroyed at the end of the study. De-identified datasets will be maintained by the Contractor. CDC will receive a copy of de-identified study data at the end of the study, and will make the aggregate data available for potential analysis by third parties based on conditions specified in a data sharing agreement. Accuracy: Contractor will check the data collected in the study database throughout the study and at the study end. Relevancy: CDC will collaborate with the Contractor 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 ☐ Developers ☒ Contractors: RCE clinic staff will have access to PII in ~~order to collect study data and to de-~~ ☐ Others
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Only RCE clinic staff (data manager, RCE Concierge, and Clinic Champion) may access clinic study records which contain PII. Only RCE clinic staff will have access to study data and encryption keys.
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 Contractor will share with RCE clinic staff during training and via the study protocol that study data will only be handled by clinic staff for the purpose(s) specified.
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 Contractor will train RCE clinic staff and Contract study staff during the pre-implementation period on proper data handling and management during study in order to protect data and ensure that staff follow the study protocol for data collection, access, management, sharing, and destruction.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	The Contractor will train RCE clinic study staff on security and privacy protocols with regards to study implementation, including use of study computers, data collection procedures (including use of the Access Database), handling, storage and transmission to the Contractor.
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.	Clinics will destroy study files after final, de-identified data are transfered to the Contractor, cleaned and verified at the end of the project. The Contractor will transfer all de-identified data to CDC. Record retention will be conducted in accordance with the CDC Scientific and Research Project Records Control Schedule ("Big Bucket").
38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	Administrative Controls: Only authorized RCE clinic study staff (the clinic-based data manager, RCE Concierge, and Clinic Champion) will have access to the project computers and their site-specific data. Clinics will de-identify data by removing names and medical record numbers and replacing them with the client's study ID. Study IDs will be linked to medical record numbers only on a clinic computer or secure server, and only RCE clinic study staff will be able to back-convert a study ID into a medical record number. Only authorized RCE clinic study staff and Contractor Study staff will have access to study-specific FTP sites. Technical Controls: The contract study staff and RCE clinic study staff will only use secure, password-protected databases; secure servers; and project computers to collect, maintain or share project files. The RCE clinic study staff will transfer de-identified data to the contractor via a secure, password-protected FTP site (each clinic will use their own FTP site). Physical Controls: Project paper files (consent forms and HIPAA authorization forms) will stored in a locked file cabinet at each clinic site. Clinic data collected as part of the study will be stored on a password-protected project computer or secure local server at the clinic in an encrypted Access database. Project databases at clinics will be destroyed when the project is completed.

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	Beverly E. Walker -S Digitally signed by Beverly E. Walker -S Date: 2022.01.20 10:11:28 -05'00'	HHS Senior Agency Official for Privacy	