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Privacy Impact Assessment Form

v 1.21

Status | Form Number: 0920-17AUZ | Form Date: 04/30/18

	Question	Answer
1	OPDIV:	CDC
2	PIA Unique Identifier:	0920-17AUZ
2a	Name:	Navigating Insurance Coverage Expansion/NICE
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: Katherine Roland POC Organization: NCHHSTP/DHPIRS/PRB POC Email: fsx3@cdc.gov POC Phone: 404-639-0982
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	Yet to be determined.
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 is to evaluate the efficacy of the in-person health insurance enrollment assistance intervention in a targeted population and evaluate the effects of the intervention. Analyses will be used to assess the efficacy of the intervention as an emerging practice. This study will evaluate the effects of the intervention on successful insurance enrollment, types of insurance coverage, rates of linkage to and retention in HIV-related healthcare among Black and Hispanic men who have sex with men (MSM) and transgender persons age 18 or older. The University of Chicago plans to collect and maintain demographic and medical record data on study participants, on behalf of CDC. The in-person assistance intervention will help Black and Hispanic MSM and transgender persons enroll in private health insurance or Medicaid at the end of their HIV testing session, regardless of their HIV status.
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 data collection system will collect and maintain participant demographic and medical record data to assess and measure changes over time after exposure to the study intervention. Participant's PII data includes name, date of birth, health insurance enrollment number, race, ethnicity, age, gender identity, and Zip code.
13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	Participant data will be housed in Research Electronic Data Capture (REDCap), a secure database system utilized by research institutions nationally. The tablets will contain portable hot spots for secure data transmission between the device and the database. The tablets will not store collected data. All participant data will be linked and stored in REDCap using a unique study ID for the participant all data will be collected by the awardee. Participant data to be collected includes demographics (date of birth, race/ethnicity, gender identity, zip code of residence, current sexual practices, current housing situation [living in own home, staying with a family member or friend, living in a temporary shelter, homeless, or in foster/group home], history of incarceration, travel time to study site), beliefs about HIV medications, substance use, mental health status, beliefs about the healthcare system, health insurance enrollment, satisfaction of study participation. Medical record data will be downloaded into the database. That information will include HIV-related clinical care, HIV test results, and viral loads.
14	Does the system collect, maintain, use or share **PII**?	(•) Yes ( ) No

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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 Zip code of residence Race/ethnicity Age Gender identity Incarceration history Participant's health insurance enrollment number
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?	500-4,999
18	For what primary purpose is the PII used?	The primary purpose of PII collection is to track eligibility.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	Secondary use of PII is to assess the changes in health outcomes.
20	Describe the function of the SSN.	N/A, not collecting SSN.
20a	Cite the **legal authority** to use the SSN.	N/A, not collecting SSN.
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: 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.	0920-17AUZ
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 — Data to be shared with CDC. ☐ Other Federal Agency/Agencies ☒ State or Local Agency/Agencies — Data to be collected by Chicago Hou ☒ Private Sector — Data to be collected by University of Chicago.
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 is an MOU between the CDC awardee; the University of Chicago Medicine, who will prepare a Data Management Plan as a requirement for their annual non-competing review and the Chicago House and Howard Brown Health.

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24c	Describe the procedures for accounting for disclosures	Sample reports will be run prior to CDC and partner agencies having access to the data to ensure that the permissions and de-identification process is working correctly. There is slight risk that identifying data could end up in the data downloads. If that were to occur, the University of Chicago's data manager would report this to the CDC within 1 hour of discovery.
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.	The study informed consent form will describe the data collection process before study participation.
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.	The consent form describes that the participant can withdraw from the study at any time. During data collection, participants are told they can skip any questions they do not want to answer.
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.	We do not anticipate major changes occurring to the system that would require participant notification.
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 consent form describes privacy procedures to protect the identity of the study participant. The consent form also provides the participant the contact information for the Human Subjects Review Board (IRB) so the participant can call if they have questions or concerns about their right as a study participant.
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.	Within the project database, there is a tracking feature. The tracking feature is an additional protection in the REDCap database to help track the security and quality of data. This feature allows University of Chicago Medicine to review who has modified, uploaded, created, and viewed records, and to quickly identify who needs to be contacted regarding potential data errors or potential breaches in privacy.
31	Identify who will have access to the PII in the system and the reason why they require access.	☐ Users ☒ Administrators: The administrator is the awardee the University of Chicago Medicine. They ☐ Developers ☒ Contractors: Howard Brown Health and Chicago House project staff, partners of the ☐ Others

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32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Within University of Chicago Medicine, only the Project Manager, Data Manager, and PI will have access to the full data set. Chicago House and Howard Brown Health project staff will be placed into a data access group, only allowing them to see the data for the participants they recruited. The University of Chicago Medicine will be able to review who has modified, uploaded, created, and viewed records, and quickly identify who needs to be contacted regarding potential data errors or potential breaches in privacy. The University of Chicago Medicine will create collaborator accounts for relevant CDC staff members and will build the necessary reports for data downloads every 6 months.
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.	Only the University of Chicago Medicine Project Manager, Data Manager, and PI will have access to the full data set. Access to the full data set is necessary for these three staff to ensure data quality and consistent management.
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.	Staff engaging in human research are required to complete research ethics training. Training includes: informed consent, data safety and monitoring, and concerns associated with conducting research with vulnerable populations. All staff are trained in proper HIPAA procedures at the time of hire. The University of Chicago Medicine research team and partner agency data managers have completed human subjects protections training and are HIPAA certified.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	All University of Chicago Medicine study coordinators will complete full day training on research methods, study procedures, and data collection. After completion of the training, a University of Chicago Medicine research team member will create training protocol for the partner agencies to ensure all related personnel are trained and understand the purpose of the study and proper research protocol. Individuals providing the intervention will complete the required Certified Application Counselor (CAC) training and will observe two sessions prior to delivering the intervention. Their first session will be observed by their study coordinator.
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.

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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.	All data, including the participant profile, will be stored within the same database utilizing a randomly generated unique record ID. Study data will not be stored on the hard drive of any partner agency computer or tablet. Computers used to access the REDCap database and study data are encrypted and password-protected. Each individual who has access to the database will have a unique username and password to log-in, enter data and access previously entered data. Hand held tablets used to collect participant data in the field will be stored in a locked cabinet, in a locked office at the University of Chicago Medicine. During data collection, tablets will be maintained by partner agency study staff. When participants are directly entering data on the tablets, it will be done under the supervision of the partner agency staff.

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
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		

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	Reviewer Questions	Answer
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: 2018.05.01 08:09:25 -04'00'	HHS Senior Agency Official for Privacy	