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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:	0920-18MY
2a	Name:	Network Epidemiology of Syphilis Transmission (NEST)
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: Robert Kirkcaldy, MD, MPH POC Organization: NCHHSTP/DSTDP/ESB POC Email: hgl8@cdc.gov POC Phone: (404) 639-8659
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	This is an information collection, not a system.
10	Describe in further detail any changes to the system that have occurred since the last PIA.	No changes. This is a new information collection.
11	Describe the purpose of the system.	The Network Epidemiology of Syphilis Transmission (NEST) study and information collection will inform development of methodologies for collection of complex sexual network data among men who have sex with men (MSM) at high risk for syphilis in the United States. NEST will address knowledge gaps about the epidemiology of syphilis among MSM in the United States.
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.)	NEST awardees will collect PII for the purpose of contacting participants for follow-up visits. Information being collected will include: name, date of birth, email address, mailing address, phone number, social media handles (Facebook, Instagram, Twitter, Snapchat), medical record number, and STD surveillance ID. Participants will describe their recent sexual network and might provide names or nicknames of recent partners to the local study site. PII will not be transmitted to the CDC. Data that will be sent to CDC include: (1) Epidemiological data such as age, sex, gender, race, ethnicity, clinical data, sexual activity, drug use, HIV status from men who have sex with men (MSM) who are at high risk for syphilis and enrolled in the study. (2) STI lab test results for syphilis, gonorrhea, chlamydia, and HIV. All study participants and named sexual partners will be assigned unique non-identifiable study participant IDs. These unique study participant IDs will not include medical record numbers or PII. The key to link data will only be available at the local level.
13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	The purpose of the study is to design interventions to reduce the spread of syphilis. The study will collect longitudinal survey data from study participants. Men who have sex with men (MSM) who are at high risk for syphilis will be enrolled into the study. Data will be collected from enrolled MSM during a standardized survey interview at each study visit. The standardized interview will ascertain basic demographic information such as Name (only collected locally), DOB(only collected locally), age, country of residence, race, ethnicity; information about healthcare access and utilization; and sexual behavioral information including sexual network information (all elements collected locally only) such as names of contacts, phone numbers, social media handle, e-mail.
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 Social Media Handles STD surveillance ID Other... Other... Other...
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 use of the PII is to allow local sites to contact participants for follow-up visits.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	The secondary use of the PII is to allow the local sites to track changes in sexual network structure and partnerships over time.
20	Describe the function of the SSN.	N/A, SSN's are not collected
20a	Cite the **legal authority** to use the SSN.	N/A, SSN's are not collected
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)).
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.	This is a new Information Collection Request.
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)).	Not applicable
24c	Describe the procedures for accounting for disclosures	N/A No data are shared or disclosed.

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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.	At the beginning of the study eligible participants will be asked to review and sign a study consent form that informs participants that personal identifying information will be collected and every effort will be made to keep this information confidential. This information will be kept secure, accessed, and retained by the recruiting sites and not transmitted to the CDC.
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 withdraw or revoke their permission to use and disclose PII and health information at any time. This will be done by sending a written notice to the local site researchers. Contact information for local site researchers will be included in the study consent form. If participants withdraw their permission, no new information identifying the participant will be gathered after that and the participant will no longer be able to stay in the study.
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.	There are no major changes expected for this information collection, however, individuals can be contacted via phone or email by local study staff to notify them of any major changes 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.	Study participants will be instructed to contact an individual in the Office of Responsible Research Practices at each local site if they have any questions about their rights as a participant or concerns that their PII may have been inappropriately obtained, used, or disclosed. Contact information will be included in the study consent form.
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.	The PII collected is held at the local sites. The local sites will confirm the accuracy of the information each time they contact a participant by phone, e-mail, and/or during study visits. If local site staff are unable to contact the participant after multiple attempts, the participant will be withdrawn from future study visits.
31	Identify who will have access to the PII in the system and the reason why they require access.	☒ Users — Local Site Staff involved in the Study for collecting and entering the data. ☐ Administrators ☐ Developers ☐ Contractors ☐ Others

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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.
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.	CDC personnel are required to complete the annual OCISO Security Awareness Training to make them aware of their responsibilities for protecting the information being collected and maintained. Local study staff will undergo data security and confidentiality training annually and will sign a confidentiality statement before access to study data is authorized. All local study staff will be knowledgeable about local data security policy and procedures and researchers will ensure that the written data security policy is easily accessible.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	Details of training is under the auspices of each local site.
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.	CDC uses the CDC Records Control Schedule for determining retention and destruction of PII, specifically, section 04-4-40 Surveillance Report of STD Activity, which prescribes that records be retained and destroyed when no longer needed for administrative or research purposes or when 30 years old, whichever comes first.

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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.	Technical Access to the server is controlled using individual access controls and only authorized users will have access to the data. Administrative CDC will not receive or store 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. CDC personnel are required to complete the annual OCISO Security Awareness Training to make them aware of their responsibilities for protecting the information being collected and maintained. Local study staff will undergo data security and confidentiality training annually and will sign a confidentiality statement before access to study data is authorized. All local study staff will be knowledgeable about local data security policy and procedures and researchers will ensure that the written data security policy is easily accessible. Physical CDC data will be stored on an ITSO supported server housed in the Application Hosting Branch (AHB). This facility is protected by Guards at the front gate entrance to the campus, additional protections include Personal Identification Verification (PIV) card access to the building and rooms where the servers are located. Guards are also located inside the campus and buildings to control ingress and egress.

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		

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	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: 2018.07.19 16:39:51 -04'00'	HHS Senior Agency Official for Privacy	