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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:	0920-18AVE New GenIC
2a	Name:	Pathways: Qualitative Interviews with Post-Partum Women Asso
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: Public Health Advisor POC Name: Jennine Kinsey POC Organization: (DSTDP)/SABRE POC Email: ire0@cdc.gov POC Phone: 404-639-6339
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	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 this qualitative information collection is to better understand and identify factors that result in deviations from the “ideal” pregnancy narrative, as well as factors that are protective, supportive, or that appear to facilitate access to and use of timely and adequate prenatal care and syphilis diagnosis and treatment during pregnancy. We will 1) document women associated with congenital syphilis (CS) cases and their recollections of and perspectives about their pregnancy and prenatal care experience, 2) attempt to identify potential protective or supportive factors that would facilitate care and reduce the risk of CS, and 3) identify strategies to reach vulnerable women and increase awareness of the risks of CS during pregnancy. Findings from the qualitative interviews will help increase sexually transmitted disease (STD) program capacity to reach women at risk for CS, and will prevent CS cases by identifying strategies for improving outreach and education to women at risk for CS.
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 recruitment script collects the participant's name that is used by the public health department during the recruitment effort. The recruiter will also ask the potential participant to confirm their identity by verifying their date of birth, which the health department representative will already have in addition to the participant's name. The "Recruitment Verification Form" is completed by the health department recruiter, who records date, respondent's name, phone number, email address and willingness to participate in the study.

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13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	The planned study design will use purposive, targeted sampling to recruit 60 case mothers to participate in an interview from all women identified as CS case mothers in 2015, 2016, or 2017 in the three sites. Data will be collected from 60 semi-structured, 90-minute long, in-person qualitative interviews using a timeline elicitation method. Data will be collected from case mothers in three CDC-funded jurisdictions: the states of California and Florida and the metropolitan statistical area (MSA) of Chicago. The number of interviews to be conducted in each site will be based on weighted averages related to disease burden, but will be approximately 20 per location. Qualitative coding and thematic analysis of 60 in-depth interview transcripts using computer-assisted qualitative data analysis software Nvivo 11. The in-depth interviews will primarily include open-ended questions with some closed-ended questions designed to elicit information on participants' pregnancy, prenatal care, and syphilis diagnosis experiences related to those events. Key variables to be explored through the interviews include demographics, experiences of pregnancy diagnoses, prenatal care during 1st, 2nd, and 3rd trimester, syphilis diagnosis, and post pregnancy experiences. Although name, date of birth, phone number, and email address data are collected, they will not be transmitted to CDC nor will any record be retrievable by any element of PII. None of the PII is linked to the study questions or study data.
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 [ ] Mailing Address [x] 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 Other... Other... Other... Other... Other...

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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 PII is to recruit potential case mothers to the study.
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.	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.	This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (Attachment 1).
22	Are records on the system retrieved by one or more PII data elements?	○ Yes ◉ No
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

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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.	0290-0840 (18AVE)
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	
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

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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 at any time. This will be done by sending a written notice to the local site researchers. Recruitment contact information for local site researchers and the recruitment verification form are separate from the study data. If participants withdraw their permission, no new information will be gathered and the participant will not participate 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.	Participants will be provided contact information and instruction to contact either the grantee principal investigators or CDC's Human Research Protection Office.	
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, email, 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 ☐ Administrators ☐ Developers ☐ Contractors ☐ Others	Users include local site staff involved in the study for collecting and entering
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Roles and responsibilities to access PII will be limited to study investigators accessing 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 PII will be restricted to Institutional Review Board (IRB) individuals trained in human subject protections. 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.	

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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).	As part of the IRB approval process, interviewers submit proof of completion of recent ethics training. This process involves substantial content regarding privacy and confidentiality. Interviewers also must commit to CDC that they will comply with Health and Human Services Protection of Human Subjects regulations 45 CFR part 46. All CDC staff earn Scientific Ethics Verification numbers as required by the IRB for engaging human subjects research. These numbers are obtained only after completing in-depth ethics trainings including sections on privacy and confidentiality.
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.
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 has defined that roles and responsibilities to access PII is limited to only study investigators with 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. Physical CDC data will be stored on a secured server at a facility protected by guards. Additional protections include Personal Identification Verification (PIV) card access protections. Guards are also located inside 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

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	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		
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

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	Reviewer Questions	Answer
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	Jarell Oshodi -S Digitally signed by Jarell Oshodi -S Date: 2018.12.11 12:56:17 -05'00'	HHS Senior Agency Official for Privacy