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Privacy Impact Assessment Form

v 1.47.4

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	Question	Answer
1	OPDIV:	CDC
2	PIA Unique Identifier:	P-8700785-433756
2a	Name:	Birth Defects Study to Evaluate Pregnancy Exposures (BD-STEPS)
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.	Operations and Maintenance
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: ISSO POC Name: Cindy Allen POC Organization: NCCDPHP POC Email: clallen@cdc.gov POC Phone: 770-488-5388
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	June 14, 2017 ☐ Not Applicable

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11	Describe the purpose of the system.	The Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS) system has been developed to identify modifiable maternal exposures in early pregnancy that may increase the risk for having a pregnancy affected by certain major, structural birth defects. The BD-STEPS interview will focus on the key areas of: (1) diabetes, obesity, and physical activity; (2) other chronic maternal medical conditions; (3) infertility; and (4) medication use.
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 system will contain health care research data such as chronic conditions, medications used during pregnancy, interview responses and mothers' experiences during pregnancy and exposures to possible risk factors. The system will also contain contact information for mothers of infants with a date of birth, or pregnancy terminations, on or after September 1, 2015 in each of the defined study regions. During the study, the participants will also provide the following information: • baby's estimated date of delivery; • baby's date of birth; • father's date of birth; • mother's email and mailing addresses; and • name and contact information (mailing address, phone number) of an additional contact in the event we have difficulty contacting the mother in the future.

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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.	In January 2014, the Centers for Birth Defects Research and Prevention (CBDRP) began collaboration on a case-control study called the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS). The purpose of BD-STEPS is to identify modifiable maternal exposures in early pregnancy that may increase the risk for having a pregnancy affected by certain major, structural birth defects. Mothers of the case infants and mothers of randomly selected live born control infants will be contacted and invited to participate in a maternal interview covering multiple topics. BD-STEPS will start data collection for infants with a date of birth, or pregnancy terminations, on or after September 1, 2015 in each of the defined study regions. Data that is contained and processed by the system will be used to - • Contact sampled study subjects to conduct interviews. These interviews will focus on the subject's experiences during her pregnancy and exposures to possible risk factors. • Conduct follow-up stillbirth interviews with a subsample of participants, as well as an additional sample of mothers who experienced a stillbirth that was not affected by a birth defect. • Conduct reminder calls with a subsample of participants to obtain consent for Centers to access their newborn bloodspots (collected by some states at birth) and reminder calls to complete an online questionnaire hosted by CDC. • Conduct all mailings associated with study activities for Atlanta CBDRP subjects only, including introductory packets that contain informed consent information and follow-up letters. In order to conduct the study activities, the system will maintain contact information for the purpose of mailing study related materials and calling study subjects for interviews, and also for mothers that had pregnancy terminations that occurred or for mothers of infants born on or after September 1, 2015 in each of the defined study regions.
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
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: Live born babies (or pregnancies if not live born) of study subjects.
17	How many individuals' PII is in the system?	10,000-49,999
18	For what primary purpose is the PII used?	PII is required to contact sampled respondents for interview.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	None
20	Describe the function of the SSN.	SSN is not used, collected or stored.
20a	Cite the **legal authority** to use the SSN.	SSN is not used, collected or stored.
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)
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:	09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC
		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.		OMB IC# 0920-0010; Expiration date 12/31/2018
24	Is the PII shared with other organizations?		◉ Yes ○ No

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24a	Identify with whom the PII is shared or disclosed and for what purpose.	☒ Within HHS Datafile might be used for further research purposes within HHS. ☐ Other Federal Agency/Agencies ☒ State or Local Agency/Agencies Abt will share PII (i.e., updated contact information) with State agencies via CDC SAMS, so that the State agencies have the most up-to-date contact information for their study mailings and other future contacts with respondents. ☒ Private Sector PII is shared with Abt via CDC SAMS to conduct research and analysis.
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)).	Data Use Agreements (DUAs) have been signed between Abt and 6 of the 7 study centers. CDC is the lead for the 7th study center, therefore no DUA is required. The DUA allows each Center to share PII with Abt; Abt to contact and collect data from each Center's study participants; and Abt to share de-identified data with CDC. Lastly, it permits the updated contact information to go back to the Center.
24c	Describe the procedures for accounting for disclosures	All requests for disclosure are to be made to the Abt Project Director and approved by CDC. Approved disclosures are compiled in an electronic spreadsheet maintained by the Project Director with the following information: --name of requester --purpose of disclosure --date of disclosure --address (email or phone) to receive information --record(s) disclosed The disclosure information will be retained in an electronic document by the contractor until the end of the project and then handed over to the CDC during project close out.
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.	Personal information will be gathered directly from study participants via phone when the project team reaches out to conduct telephone interview data collection. A verbal consent process is conducted before the launch of the telephone interview.
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.	Initial PII is provided to the contractor (on CDC's behalf) by the state health department. The contractor, Abt, contacts individuals for participation in the research study, and the individuals can then opt out of participation in the study and their personal information is then deleted from the information collection. However, if they do not opt out of participation, their personal information is maintained as it is needed for further contact and use.

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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.	If disclosure/data uses change, the Data Use Agreement between each Center and Abt would be revised to reflect the changes. Each Center would be responsible for contacting their IRB to determine if participants needed to be notified of the change. If necessary, the study newsletter that is available to each participant would be updated by CDC to reflect the change and would allow participants to contact study staff to request additional information and/or withdraw from the study.
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.	Before Abt contacts any study participants by telephone, participants are sent an advance packet by each study Center. The advance packet includes a Rights of Research Subjects flyer, which directs participants to contact the CDC Human Research Protection Helpline with any concerns about their rights as study subjects and their data. At the start of each interview, Abt staff will advise study participants to contact their study Center if they have any concerns about the study and the use of their data. Abt staff will also direct study participants to either the local study Center IRB or CDC's IRB (depending on the Center) if they have any questions about their rights as a study subject and the use of their data. Abt will work with CDC and each local Center to resolve any study participant concerns.
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.	Abt staff confirm the accuracy of PII at each contact with the study subject, including during the interview survey and when sending follow-up mailings (reminder and thank you letters).
31	Identify who will have access to the PII in the system and the reason why they require access.	☒ Users: Require access to information to perform analysis and research. ☒ Administrators: Administrators require access for troubleshooting. ☐ Developers: ☒ Contractors: Require access to perform analysis and research. ☐ Others:
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Role based access methodologies are employed to determine which users may access PII.
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 Least privilege model is used to ensure that those having access to PII can access only minimal amount of PII necessary to perform their job responsibilities.

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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.	Abt provides basic security awareness training to all information system users (including managers, senior executives, and contractors) as part of initial training for new users, when required by system changes, and annually thereafter. The training is tracked and provided through Abt's Learning Management System (LMS). The topics in the training include safe handling of PII, incident response, phishing, and password management.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	Abt provides role-based training (RBT) at least once a year and prior to authorizing access to the system. Study-specific training for interviewers on how to conduct the survey interviewing is conducted before the project goes live.
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.	Abt retains documents as required by CDC. By default, data is stored by Abt for 5 years on tape. Data security plans are developed per project as appropriate and define the data destruction timelines for the project. CDC will retain the records for 20 years; or longer if further study is needed. The specific Records Schedule Number is N1-442-09-1.
38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	The system developed to support this project has been designed using the National Institute of Standards and Technology Special Publication 800-53 revision 4. The system has defined policies and procedures for account creation and system management. To protect the files, Microsoft Windows Active Directory controls folder permissions through discretionary access control. User accounts have strong password requirements, and all mobile devices that store the data utilize FIPS 140-2 full device encryption. The data are physically stored within facilities that have keycard access and the servers are within another keycard access server room. The facility has cameras, alarms, and fire suppression systems.

General Comments	

OPDIV Senior Official for Privacy Signature	Beverly E. Walker -S Digitally signed by Beverly E. Walker -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1001440343, cn=Beverly E. Walker -S Date: 2017.06.26 12:41:14 -04'00'