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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date 03/22/23

	Question	Answer
1	OPDIV:	CDC
2	PIA Unique Identifier:	TBD
2a	Name:	Population-based surveillance of outcomes, needs, and well-bei
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.	Planning
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: Health Scientist POC Name: Karrie Downing POC Organization: NCBDDD POC Email: yyx9@cdc.gov POC Phone: 404.498.0710
7	Is this a new or existing system?	◉ New ○ Existing
8	Does the system have Security Authorization (SA)?	◉ Yes ○ No
8a	Date of Security Authorization	REDCap PIA ATO is 8-26-2022

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10	Describe in further detail any changes to the system that have occurred since the last PIA.	Previous PIA was approved to conduct the survey though mail only . Survey participants will also be given the option to take the survey online in REDCap. Funded sites have been identified.
11	Describe the purpose of the system.	This project will gather information on cardiac and other healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care planning from childhood to adulthood, and mortality of children and adolescents (ages 2-17 years) with Congenital Heart Defects (CHD) as well as needs and experiences of their caregivers. The children and adolescents will be identified as being born with a CHD through birth defects surveillance systems from funded sites (Boston University, Minnesota Department of Health) and Metro-Atlanta. Once identified, the sites will send the children's parents or caregivers information on the project, a passive consent form, a paper survey, and a link to take the survey online via REDCap if preferred. The de-identified answers to the survey questions will be linked to de-identified information gathered at birth from the birth defects surveillance systems using a code. The de-identified data will be analyzed and results will be shared in peer-reviewed publications, national and local meetings, and with public health stakeholders focused on children and adolescents with CHD. This project fills a gap in available information on children and adolescents living with CHD. The information will help children with CHD and their families receive better care and plan for their future.
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.)	At each site, data from the birth defect surveillance systems will be linked to death records to determine vital status of each child or adolescent with CHD and year of death for those deceased. For those not determined to be deceased, each site will track the parent or caregiver using data from the birth defect surveillance system to determine their current contact information. Each site will mail parents information on the project, a passive consent form, a paper survey and a link to take the survey online via REDCap if preferred. The survey inquires about the cardiac and other healthcare utilization, barriers to health care, quality of life, social and educational outcomes, and transition of care planning from childhood to adulthood of their child with CHD as well as the needs and experiences of the parents or caregivers. To receive project updates, participants may also provide their email address on the paper survey or on paper after survey completion for those completing it online. The de-identified survey data will be linked to the de-identified birth defect surveillance system data to include information on the child's diagnoses at birth and information about their gestation and birth such as gestational age at birth, plurality, birth weight, birth year, sex, and maternal race.

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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.	Parents or caregivers of children and adolescents (ages 2-17 years) with CHD, identified from three birth defects surveillance systems, will be sent a ~20-minute survey asking about their child's health, social, educational, and other outcomes as well as needs and experiences of the caregivers. In addition, the survey asks the parent or caregiver for an email address if they would like to receive periodic updates on the results of project. Completed surveys will be collected and stored at CDC. Participants will be assigned a random number as their participant ID for the project. This participant ID will be linkable to their current contact information, which is not included in this system or shared between sites. CDC will notify sites of participant IDs who have completed a survey so that the sites can mail those participants a thank you letter as appreciation for their time and effort to complete the survey. De-identified survey data will be linked to de-identified birth defects surveillance data and shared across sites. Email addresses of survey participants will be stored separately from survey answers. Results of this project will be disseminated to individuals living with CHD and their families, CHD organizations, health researchers, and physicians through papers, presentations, and other documents. This information will fill a gap in the knowledge on health and well-being of children and adolescents living with CHD. We plan to disseminate results of this project to individuals living with CHD and their families, CHD organizations, health researchers, and physicians through papers, presentations, and other documents. Data sources includes: Birth defects surveillance systems from funded sites (Boston University, Minnesota Department of Health) and Metro-Atlanta Participant authentication: Each survey participant will receive a QR code that takes them directly to their individual online survey. They will receive their QR code via mail. Physical access to the QR code will be the only point of authentication for the participant. They will not have to enter any additional information online to get to their specific online survey. They will not have access to anything other than their specific online survey in REDCap. Staff authentication: CDC staff will be accessing REDCap via SAMS, which requires an authenticated SAMS account, a CDC SmartCard, and pin."
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 Birth weight Particpant ID Sex Gestational age at birth Maternal race
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?	5,000-9,999
18	For what primary purpose is the PII used?	Names and dates of birth from the birth defect surveillance systems will be used at each site to track and trace the current contact information (current name, mailing address, and phone number) of parents or caregivers of eligible children with congenital heart defects to mail survey packets to their current address. The PII from each site's surveillance system and tracking and tracing efforts, remains at each site and is not shared across sites. To receive project updates, participants may also provide their email address on the paper survey or on paper after survey completion for those completing it online, mailed to CDC. CDC will email project updates individually to parents who request them and provide their email address. Participants will be assigned a random number as their participant ID for the project. This participant ID will be linkable to their current contact information, which is not included in this system or shared between sites. CDC will notify sites of participant IDs who have completed a survey so that the sites can mail those participants a thank you letter as appreciation for their time and effort to complete the survey.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	Not applicable

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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.	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
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 Surveilla 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 Control Number: 0920-1382, Exp. date: 1/31/2026
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 ☐ 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.	The survey is completed by the parents of children with CHD, who may choose to provide an email address to CDC if they are interested in receiving periodic updates on the project.
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 informational letter, consent form, and the survey itself, state that the individual can skip any question on the survey. The participants will also be provided a name, email, and phone number of a project coordinator, if they have additional questions or wish to opt-out of the project.
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.	Funded sites will be responsible for notifying participants of major changes to the use of participant data, if changes are made. Sites may use differing methods to communicate this information to survey participants. No change of this type is anticipated to take place throughout the course of the project.
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.	Potential and participating individuals who have concerns about the use/misuse/inaccuracy of their PII can contact the project site and request for the information to be corrected or withdrawn - A name, email, and phone number of a project site coordinator will be provided in the survey mailing. Participants at any point in the project and after can request to be removed from the project.
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 project data analyst will initially conduct a quality assurance step comparing name and address on the survey materials, the information gathered during tracking and tracing and the information in the birth defects registries to ensure accuracy. Inaccurate or irrelevant information will be removed from the system. Ongoing review of data entry accuracy will occur during double data entry and regular quality checks of the project dataset.

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31	Identify who will have access to the PII in the system and the reason why they require access.	☐ Users	
		☒ Administrators	Comparing the name and address on the survey materials, the information
		☐ Developers	
		☒ Contractors	Tracking and tracing for current contact information. Preparation and
		☒ Others	CDC PI, supervision of all project staff
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	All individuals who have access to PII must receive prior mandatory ethics training, assurance of confidentiality training, and additional CDC training on confidentiality procedures related to birth defects registries.	
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.	User roles are implemented to limit information displayed to individual users, both for functional as well as security purposes. Information displayed to a particular role is limited to necessary "need to know" information based on a specific role's required tasks throughout the project.	
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.	These individuals receive annual mandatory CDC training on assurance of confidentiality and confidentiality procedures specific to birth defects registries. Once confidentiality training is complete, personnel must sign a confidentiality agreement that indicates that the signee has carefully read and understands the agreement and the confidentiality of all records handled. Confidentiality training must be received before an individual is allowed access to project data containing PII. Confidentiality training is renewed every 365 days.	
35	Describe training system users receive (above and beyond general security and privacy awareness training).	CDC staff and contractors who have access to project PII receive confidentiality training. This training covers the procedures and practices to protect the confidentiality of the data collected or distributed. Project personnel (students, data managers, project coordinators, PI) are required at all times to maintain and protect the data and confidential records that may come into their presence and under their control. This training covers, but is not limited to, the following areas of concern: restrictions on use of information, enhanced protection of computerized files as part of implementation, dissemination of research results, data sharing with other study partners, analytic data access policies and procedures, instructions concerning confidentiality procedures, procedures for traveling with confidential study materials, and loss of study materials containing confidential data. Once confidentiality training is complete, personnel must sign a confidentiality agreement that indicates that signee has carefully read and understands the agreement and the confidentiality of all records handled. In addition, personnel in specific roles receive training and awareness related to those roles as needed, e.g., computer system administrators and other IT personnel receive training on computer system security.	
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	◉ Yes ○ No	

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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 in accordance with Scientific and Research Project Records Control Schedule N1-442-09-01. PII will be removed before records are archived. Contractors will transfer relevant records before the end of the award. Identifying information (email address) will be collected during the data collection period. During data cleaning, email address will be separated from other survey elements and stored in a separate file on a restricted-use folder on a CDC server. Only the research staff will have access to a list linking a participant's PII to his/her de-identified survey and birth defect surveillance system data. All project data will be stored at the CDC in restricted use files only accessible to specific project staff who have received confidentiality training and signed a confidentiality agreement.

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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.	Administrative Controls: Project staff receive Assurance of Confidentiality training and birth defect registry-specific confidentiality training. This training covers the procedures and practices to protect the confidentiality of the data collected or distributed. Project personnel (CDC staff, contractors, students) are required at all times to maintain and protect the survey data and confidential records that may come into their presence and under their control. This training covers, but is not limited to, the following areas of concern: restrictions on use of information, enhanced protection of computerized files as part of study implementation, dissemination of results, data sharing with other partners, analytic data access policies and procedures, instructions concerning confidentiality procedures, procedures for traveling with confidential materials, and loss of survey materials containing confidential data. Once confidentiality training is complete, personnel must sign a confidentiality agreement that indicates that signee has carefully read and understands the agreement and the confidentiality of all records handled. Technical Controls: Access to PII follows a least privilege model. The PII is secured in restricted-use folders within the CDC electronic system. Secure logins and using key cards and passcodes prevent unauthorized access to the project data. Roles will be utilized to prevent unnecessary viewing of PII. Storage will utilize FIPS-compliant encryption. Server room remains locked at all times through the use of RFID key cards and personal security passcodes assigned to individual authorized IT staff with proper security privileges. Physical Controls: Physical measures, policies, and procedures are in place at the CDC office to protect information, buildings, and equipment from unauthorized intrusions, environmental hazards, and natural hazards. PII is stored in a separate cabinet and room than the other survey information. The survey information is stored in locked filing cabinets in the office of the PI, which remains locked when not in use. After data entry is complete, any data collected on paper is stored in a secured file room with keyed access by only two individuals.

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		

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	Reviewer Questions	Answer
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
Reviewer Notes		
12	Were any changes made to the system because of the completion of this PIA?	◯ Yes ◯ No

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Reviewer Questions	Answer
Reviewer Notes	
General Comments	
OPDIV Senior Official for Privacy Signature	Beverly E. Walker -S Digitally signed by Beverly E. Walker -S Date: 2023.05.18 19:08:09 -04'00'
HHS Senior Agency Official for Privacy	