

Privacy Impact Assessment Form

v 1.21

Status Form Number Form Date

Question

Answer

1 OPDIV:

CDC

2 PIA Unique Identifier:

TBD

2a Name:

Caring for Individuals with Congenital Heart Defects (CHD), Mus

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
 POC Name
 POC Organization
 POC Email
 POC Phone

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

8c	Briefly explain why security authorization is not required	
9	Indicate the following reason(s) for updating this PIA. Choose from the following options. <input type="checkbox"/> PIA Validation (PIA Refresh/Annual Review) <input type="checkbox"/> Anonymous to Non-Anonymous <input type="checkbox"/> New Public Access <input type="checkbox"/> Internal Flow or Collection <input type="checkbox"/> Commercial Sources <input type="checkbox"/> Significant System Management Change <input type="checkbox"/> Alteration in Character of Data <input type="checkbox"/> New Interagency Uses <input type="checkbox"/> Conversion PRA	
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 National Center on Birth Defects and Developmental Disabilities (NCBDDD) performs surveillance and research for birth defects, including congenital heart defects (CHD), muscular dystrophies (MD), and spina bifida (SB). NCBDDD has a requirement for the implementation of focus groups to collect qualitative information on the experiences of persons with CHD, MD, and SB (and in some instances, their caregivers). This requirement is needed to address gaps in the literature, inform future surveillance, research, and data collection, and gather patient and caregiver perspectives that may be shared with clinicians and inform clinical care. The objective of this project is to conduct 46 focus groups to obtain firsthand perspectives on the types of care adults (18 years and older) with MD, SB, and CHD receive with a special focus on: medical care (including specialist care) and barriers and facilitators to accessing, receiving, or reengaging in care; experiences around the transition from pediatric to adult care; experiences with clinics that provide care according to specific care considerations; and the journey to diagnosis. Also, for MD and SB, perspectives will be gathered from caregivers of children with specific condition types. Each focus group shall be virtual (i.e., conducted using chat and recording-enabled videoconferencing software), include a minimum of 5 and maximum of 8 participants, and last 90 minutes. A third-party web-based screening surveys tool will be used to determine the eligibility of adults interested in participating in the focus groups and invite them to participate in a focus group. The transcripts from the focus groups will be compiled by condition type. The data will be analyzed, and results will be shared in peer-reviewed publications, national and local meetings, and with public health partners focused on adults with CHD, MD, or SB. Data from this project will enable federal, state, and local governments and organizations to understand the perceived barriers to specialty care for adults with CHD, MD, and SB, allocate resources, and establish programs accordingly.	

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.)

All data maintained by the contractor will be destroyed at the end of the project. Project period is 3 years.

1. CHD recruitment list will be provided to contractor by CDC: will include name and contact information. The contractor will provide updated contact information to the CDC.
2. CHD, MD, and SB screening/recruitment (collected/maintained by contractor): will include demographics, healthcare utilization, health status, insurance status/type, urban/rural status, employment status, annual household income, defect type, email (only for eligible individuals).
3. Focus Groups (Information collected/maintained by contractor): will include transcript of 90-minute virtual focus group and demographics for each virtual focus group.

13 Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.

The contractor will obtain contact information (name, email, phone, mailing address) during recruitment for MD and SB focus groups. This information will not be shared with the CDC. The CDC will provide contact information (name, email, mailing address) from another system (formerly CH-STRONG) participants that consented to follow-up. The contractor will use this CDC provided list of individuals to track and trace current contact information and then recruit for CHD focus group participation. The contractor will send CDC the updated contact information and notify them of those on the list that will participate in the CHD focus groups.

The focus group screening tools will collect the following information: race/ethnicity, preferred language of communication, age in years, sex, state of residence, urban/rural status, employment, annual household income, education level, insurance status/type, healthcare utilization, defect type, name, email, phone number. The information collected on the screening instrument will only be shared with the CDC in aggregate reports.

The focus group sessions will be recorded, transcribed, and analyzed by the contractors, and reports will be generated for each focus group and by overall themes by defect type. All data from the focus group sessions will be deidentified when sent to the CDC.

14 Does the system collect, maintain, use or share PII? Yes No

<p>15 Indicate the type of PII that the system will collect or maintain.</p>	<table border="0"> <tr> <td><input type="checkbox"/> Social Security Number</td> <td><input type="checkbox"/> Date of Birth</td> </tr> <tr> <td><input checked="" type="checkbox"/> Name</td> <td><input type="checkbox"/> Photographic Identifiers</td> </tr> <tr> <td><input type="checkbox"/> Driver's License Number</td> <td><input type="checkbox"/> Biometric Identifiers</td> </tr> <tr> <td><input type="checkbox"/> Mother's Maiden Name</td> <td><input type="checkbox"/> Vehicle Identifiers</td> </tr> <tr> <td><input checked="" type="checkbox"/> E-Mail Address</td> <td><input checked="" type="checkbox"/> Mailing Address</td> </tr> <tr> <td><input checked="" type="checkbox"/> Phone Numbers</td> <td><input type="checkbox"/> Medical Records Number</td> </tr> <tr> <td><input type="checkbox"/> Medical Notes</td> <td><input type="checkbox"/> Financial Account Info</td> </tr> <tr> <td><input type="checkbox"/> Certificates</td> <td><input type="checkbox"/> Legal Documents</td> </tr> <tr> <td><input type="checkbox"/> Education Records</td> <td><input type="checkbox"/> Device Identifiers</td> </tr> <tr> <td><input type="checkbox"/> Military Status</td> <td><input checked="" type="checkbox"/> Employment Status</td> </tr> <tr> <td><input type="checkbox"/> Foreign Activities</td> <td><input type="checkbox"/> Passport Number</td> </tr> <tr> <td><input type="checkbox"/> Taxpayer ID</td> <td><input type="text" value="Sex/Gender"/></td> </tr> <tr> <td><input type="text" value="Race/Ethnicity"/></td> <td><input type="text" value="Education level"/></td> </tr> <tr> <td><input type="text" value="Age"/></td> <td><input type="text" value="Defect Type"/></td> </tr> </table>	<input type="checkbox"/> Social Security Number	<input type="checkbox"/> Date of Birth	<input checked="" type="checkbox"/> Name	<input type="checkbox"/> Photographic Identifiers	<input type="checkbox"/> Driver's License Number	<input type="checkbox"/> Biometric Identifiers	<input type="checkbox"/> Mother's Maiden Name	<input type="checkbox"/> Vehicle Identifiers	<input checked="" type="checkbox"/> E-Mail Address	<input checked="" type="checkbox"/> Mailing Address	<input checked="" type="checkbox"/> Phone Numbers	<input type="checkbox"/> Medical Records Number	<input type="checkbox"/> Medical Notes	<input type="checkbox"/> Financial Account Info	<input type="checkbox"/> Certificates	<input type="checkbox"/> Legal Documents	<input type="checkbox"/> Education Records	<input type="checkbox"/> Device Identifiers	<input type="checkbox"/> Military Status	<input checked="" type="checkbox"/> Employment Status	<input type="checkbox"/> Foreign Activities	<input type="checkbox"/> Passport Number	<input type="checkbox"/> Taxpayer ID	<input type="text" value="Sex/Gender"/>	<input type="text" value="Race/Ethnicity"/>	<input type="text" value="Education level"/>	<input type="text" value="Age"/>	<input type="text" value="Defect Type"/>
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<input type="checkbox"/> Medical Notes	<input type="checkbox"/> Financial Account Info																												
<input type="checkbox"/> Certificates	<input type="checkbox"/> Legal Documents																												
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<p>16 Indicate the categories of individuals about whom PII is collected, maintained or shared.</p>	<table border="0"> <tr> <td><input type="checkbox"/> Employees</td> </tr> <tr> <td><input checked="" type="checkbox"/> Public Citizens</td> </tr> <tr> <td><input type="checkbox"/> Business Partners/Contacts (Federal, state, local agencies)</td> </tr> <tr> <td><input type="checkbox"/> Vendors/Suppliers/Contractors</td> </tr> <tr> <td><input type="checkbox"/> Patients</td> </tr> <tr> <td>Other <input type="text"/></td> </tr> </table>	<input type="checkbox"/> Employees	<input checked="" type="checkbox"/> Public Citizens	<input type="checkbox"/> Business Partners/Contacts (Federal, state, local agencies)	<input type="checkbox"/> Vendors/Suppliers/Contractors	<input type="checkbox"/> Patients	Other <input type="text"/>																						
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<p>17 How many individuals' PII is in the system?</p>	<input type="text" value="500-4,999"/>																												
<p>18 For what primary purpose is the PII used?</p>	<input type="text" value="PII will only be used by the contractor to track and trace, and recruit individuals for participation in the focus groups. Focus Group responses and demographics will be deidentified and shared with the CDC in aggregate form. All PII and other data maintained by the contractor will be destroyed by the contractor at the end of the project."/>																												
<p>19 Describe the secondary uses for which the PII will be used (e.g. testing, training or research)</p>	<input type="text" value="Not applicable"/>																												
<p>20 Describe the function of the SSN.</p>	<input type="text" value="Not applicable"/>																												
<p>20a Cite the legal authority to use the SSN.</p>	<input type="text" value="Not applicable"/>																												
<p>21 Identify legal authorities governing information use and disclosure specific to the system and program.</p>	<input type="text" value="Not applicable"/>																												
<p>22 Are records on the system retrieved by one or more PII data elements?</p>	<p style="text-align: right;"> <input type="radio"/> Yes <input checked="" type="radio"/> No </p>																												

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.

Pending submission of 30-days package

24 Is the PII shared with other organizations?

Yes

No

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.

CDC participants listing that have consented are contacted to participate in a focus group or interview. Participation may refuse to answer any question for any reason, and may also stop participating at any time, for any reason, without penalty. 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.

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 mailer and screening tool states that "Participation in the focus group or interview is voluntary and participants may refuse to answer any question for any reason, and may also stop participating at any time, for any reason, without penalty". 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.

The contractor will be responsible for notifying participants of major changes to the use of participant data, if changes are made. The contractor may use differing methods to communicate this information to focus group participants.

<p>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.</p>	<p>Potential and participating individuals who have concerns about the use/misuse/inaccuracy of their PII can contact the contractor and request for the information to be corrected or withdrawn. A name, email, and phone number of a project coordinator will be provided on the screening tool along with any mailing or email communications. Participants at any point in the project and after can request to be removed from the project.</p>											
<p>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.</p>	<p>Integrity: Inaccurate or irrelevant information (e.g., incorrect email addresses or phone numbers from the CHD list or screener data) will be removed from the system in year 1 and will be reviewed again for accuracy and integrity on an annual basis in years 2 and 3.</p> <p>Availability: Aside from the CHD contact list, which will be provided to the contractor by CDC, the data collected for this project are based on participant response.</p> <p>Accuracy: The contractor will perform tracking and tracing to confirm vital status and contact information for individuals on the CHD list annually in years 1 and 2. For the focus group transcripts, the contractor will use transcribing software. Contract staff will review the final transcripts for accuracy and removal of any PII prior to submission to CDC annually in years 2 and 3.</p> <p>Relevancy: Only PII that is needed of study participants will be maintained in the system. All PII and data maintained by the contractor will be destroyed at the end of the project.</p>											
<p>31 Identify who will have access to the PII in the system and the reason why they require access.</p>	<table border="0"> <tr> <td><input type="checkbox"/> Users</td> <td><input type="text"/></td> </tr> <tr> <td><input type="checkbox"/> Administrators</td> <td><input type="text"/></td> </tr> <tr> <td><input type="checkbox"/> Developers</td> <td><input type="text"/></td> </tr> <tr> <td><input checked="" type="checkbox"/> Contractors</td> <td>Indirect contractor; is a prime contractor help perform screening/</td> </tr> <tr> <td><input type="checkbox"/> Others</td> <td><input type="text"/></td> </tr> </table>	<input type="checkbox"/> Users	<input type="text"/>	<input type="checkbox"/> Administrators	<input type="text"/>	<input type="checkbox"/> Developers	<input type="text"/>	<input checked="" type="checkbox"/> Contractors	Indirect contractor; is a prime contractor help perform screening/	<input type="checkbox"/> Others	<input type="text"/>	
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<input type="checkbox"/> Others	<input type="text"/>											
<p>32 Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.</p>	<p>All individuals who have access to PII must receive prior mandatory ethics training, assurance of confidentiality training, and any additional CDC training as outlined in the task order. Within 30 days of the contract award, the contractor and contractor employees submitted Non-Disclosure Agreements (NDA) to the CDC Contracting Officer.</p>											

<p>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.</p>	<p>Staff from the contract team will only have access to servers and data files containing information that is relevant to their tasks. Specifically, demographic information and contact information will be stored separately and available only to staff with a legitimate need for that information. Contact information will only be available to recruitment staff at the contractor's vendors, and only in the context of their role in scheduling focus groups and distribution of incentives to those who participated in the focus groups. At no point will CDC or the contractor access or store participants' contact information.</p>	
<p>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.</p>	<p>The contract team is required to complete the following training:</p> <ul style="list-style-type: none">• HHS/CDC Contractor Information Security Awareness, Privacy, and Records Management training: To be completed before performing work on the contract and then annually for the life of the contract.• Role-based Training: To be completed by contract staff with significant security responsibilities, in accordance with HHS policy and the HHS Role-Based Training of Personnel with Significant Security Responsibilities Memorandum <p>The contract team is required to provide documentation of completed training to the CDC Contracting Officer's Representative (COR).</p>	
<p>35 Describe training system users receive (above and beyond general security and privacy awareness training).</p>	<p>In addition to mandatory information security-related training upon hiring for new staff and annual 'Code of Conduct' training on security, privacy, and confidentiality, the contractor provides on-demand training to team members assigned to projects that may involve data classified as restricted (i.e., personal information, financial information, regulated data, etc.). Also, software engineers who contribute code to any project are required to complete training for Secure Software Delivery (e.g., courses in Foundations of Software Security, Software Security Testing & Remediation, Network & database Security, etc.).</p>	
<p>36 Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?</p>	<p><input checked="" type="radio"/> Yes <input type="radio"/> No</p>	
<p>37 Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific records retention schedules.</p>	<p>As part of contract closeout and at expiration of the contract, the contractor team must provide documentation to the CDC COR to certify that all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization. The contractor team will destroy all focus group audio recordings, notes, transcriptions, and data files at the end of contract. Any physical record will be shredded and professionally disposed of with a secure disposal company. For electronic records, the contractor team will execute the record disposal while observed by their parent company. After disposal, the parent company will provide a Certificate of Data Destruction to the CDC COR.</p>	

38 Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

Administrative: No one outside of the contractor will have access to the data saved on the contractor's secure server. All files containing PII will be secured with a password which will only be provided to those with a legitimate need to access these files for use in this project will know the file password.

Technical: Any files containing participant PII will be both password-protected and encrypted for safe storage on the contractor's secure cloud-based Microsoft SharePoint server.

Physical: All project files, including but not limited to screening data, focus group audio recordings, transcriptions, code books, data files, and summary reports, will be saved on the contractor's secure server. In addition, the contractor uses organizational measures to prevent unauthorized persons from gaining access to facilities where any sensitive data are processed (e.g., access control system [ID reader], door locking, security staff, etc.).

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?	<input type="radio"/> Yes <input type="radio"/> 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?	<input type="radio"/> Yes <input type="radio"/> 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?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes		
4	Does the PIA appropriately describe the PII quality and integrity of the data?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes		
5	Is this a candidate for PII minimization?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes		
6	Does the PIA accurately identify data retention procedures and records retention schedules?	<input type="radio"/> Yes <input type="radio"/> No
Reviewer Notes		

Reviewer Questions		Answer	
7	Are the individuals whose PII is in the system provided appropriate participation?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
8	Does the PIA raise any concerns about the security of the PII?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
9	Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
10	Is the PII appropriately limited for use internally and with third parties?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
11	Does the PIA demonstrate compliance with all Web privacy requirements?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
12	Were any changes made to the system because of the completion of this PIA?	<input type="radio"/> Yes <input type="radio"/> No	
Reviewer Notes	<input type="text"/>		
General Comments	<input type="text"/>		
OPDIV Senior Official for Privacy Signature	<input type="text"/>	HHS Senior Agency Official for Privacy	<input type="text"/>