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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date 02/13/18

	Question	Answer
1	OPDIV:	CDC
2	PIA Unique Identifier:	0920-17ADR
2a	Name:	The Study to Explore Early Development, Teen Follow-Up Study
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: IT ProjectManager POC Name: Andrew Autry POC Organization: NCBDDD POC Email: aea6@cdc.gov POC Phone: 404-498-3876
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	TBD ☐ Not Applicable

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8c	Briefly explain why security authorization is not required	
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 purpose of SEED Teen is to collect data on enrolled children's health and development when they are teenagers. Children ages 13-17 years will be identified from four of the six SEED 1 sites in Georgia, Maryland, North Carolina, and Pennsylvania. Data will be collected from three groups of children: children with Autism Spectrum Disorders (ASD), children with other (non-ASD) developmental conditions (developmental disability [DD] comparison group), and children from the general population who were initially sampled from birth records. The data collected in SEED Teen will be combined with data collected during the original SEED case-control study. Thus, SEED Teen provides a unique and rich opportunity to examine the long-term health and developmental trajectory of children in each of the three study groups and how this trajectory might be related to various demographic, maternal pregnancy, and early childhood health and behavioral factors that were collected in the SEED case-control study, 7-13 years earlier. The information collected in SEED Teen will be used to conduct epidemiological analyses to assess 1) the developmental trajectory of children identified at young ages of having ASD in comparison to children with other non-ASD developmental disabilities (DDs) and children in the general population; 2) the health and functioning of adolescents with ASD and other DDs in comparison to adolescents in the general population; 3) the healthcare utilization and needs of adolescents with ASD and other DDs in comparison to adolescents in the general population; 4) the education attainment and needs of adolescents with ASD and other DDs in comparison to adolescents in the general population; and 5) family impacts associated with having a child with ASD or other DD with the goal of identifying strategies to help meet the unique needs of these families.
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.)	SEED Teen will use contact information collected during SEED 1 to contact participants for SEED Teen to include: Name, Mother's maiden name, phone number, address and email address. SEED Teen questions will include questions on sensitive topics including children's specific health conditions, details about children's current functioning and diagnosed disabilities, children's need for special services, adverse events in children's lives such as bullying, stressful life events experienced by the child and family, parental expectations for the child's future, parent's health conditions including diagnosed mental health disorders, parent's relationship with the child, family use of social services such as food stamps, and household income.

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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.	SEED Teen will assess the health and functioning in a cohort of teens previously diagnosed with autism spectrum disorder (ASD) and other developmental disabilities (DDs) when they were young. The study will also assess family impacts associated with ASD and other DDs, and service needs and use associated with having and ASD and other DDs during the early teen years. Data from SEED Teen will include contact information as well as other PII and will enable investigators to increase scientific understanding of the developmental trajectory and health consequences of ASD among adolescents, enable federal. state, and local governments and organizations to better understand the needs of adolescents with ASD.
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 ☒ 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
17	How many individuals' PII is in the system?	500-4,999
18	For what primary purpose is the PII used?	The study will use PII from SEED 1 participants who consented to being contacted for future studies to recontact them for potential participation in SEED Teen. The PII data collected in SEED Teen such as demographics and employment status will be combined with data collected during the original SEED 1 case-control study for epidemiological analyses such as to better understand the family's use of social services.

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19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	Genetic data obtained from biosamples collected in the core SEED 1 case-control protocol will be shared with two genetic research consortia established and maintained by the National Institutes of Health for additional research. The PII collected will be used to maintain contact with the participants throughout the course of the study and (if the participant consents), this information may be retained for future contact for a follow-up study.
20	Describe the function of the SSN.	SSN is not collected or used.
20a	Cite the **legal authority** to use the SSN.	N/A
21	Identify **legal authorities** governing information use and disclosure specific to the system and program.	N/A
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 No. 0920-17ADR

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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: maximize the use of the SEED biorepository data. ☒ Other Federal Agency/Agencies: Purpose maximize the use of the SEED biorepository data. ☐ 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)).	With participants permission, SEED will share mother and child's health, genetic and behavior information (collected during our study in 2007-2011) with NDAR and dbGaP. Before sharing any data, all identifying information such as name, address, and phone number, will be replace with a code number. Both NDAR and dbGAP are restricted. Researchers who want to use these data must apply in writing to NIH for permission. Once they are approved, researchers must follow NIH policies to access and use the data in a secure way. The dbGaP is an NIH database that has genetic data from studies of a number of conditions. For more information, go to http://www.ncbi.nlm.nih.gov/gap.
24c	Describe the procedures for accounting for disclosures	The CDC data sharing administrator must be notified of any authorized or unauthorized disclosures as soon as possible. The CDC data sharing administrator will track all disclosures in a document stored in a CDC network folder. An accounting of all disclosures that have been made of an individual's record(s) may be requested by the subject individual, in writing to the data sharing administrator.
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 are notified of what data will be collected from them and how this data will be used over the phone with study staff. Parents/caregivers who provide verbal consent to enroll in SEED Teen will receive a data collection packet mailing that includes two questionnaires and consent. Telephone support will also be available to those participants to answer questions about consent and to assist completing any or all portions of the questionnaires.
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 opt out by not joining the study or by contacting the SEED Teen study staff and indicate they wish to withdraw from 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.	SEED Teen sites will be responsible for notifying study participants of major changes to the use of participant data, if changes are made. Sites may use differing methods to communicate this information to study participants. No change of this type is anticipated to take place throughout the course of the study.

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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.	All sites will follow procedures outlined in the SEED Teen protocol. Potential and participating individuals who have concerns about the use/misuse/inaccuracy of their PII can contact the study site, study PI, the governing IRB for the SEED Teen site, as well as request for the information to be corrected or withdrawn. Participants at any point in the study and after can request to be removed from the study.	
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.	SEED Teen sites initially conduct a quality assurance step comparing contact and demographic information gathered from SEED 1 to the information gathered from participants in SEED Teen. Inaccurate or irrelevant information is removed from the system. Ongoing review of data entry accuracy occurs during double data entry.	
31	Identify who will have access to the PII in the system and the reason why they require access.	☒ Users	To identify the persons who the questionnaire data belong to.
		☒ Administrators	For system administration only.
		☒ Developers	For system development and maintenance.
		☒ Contractors	For review and quality assurance prior to sharing with CDC
		☐ Others	
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	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 study.	
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 study.	
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.	Training and awareness is provided to personnel to make them aware of their responsibilities for protecting the information collected and maintained by SEED personnel. This training includes IRB training which is supplemented by study specific training on study specific confidentiality requirements. 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 in regard to the SEED study. IRB and confidentiality training must be received before an individual is allowed access to study data. Confidentiality training is renewed every 365 days, and protection of human subjects (IRB) training is renewed every 2 years.	

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35	Describe training system users receive (above and beyond general security and privacy awareness training).	SEED study users receive study specific confidentiality training in addition to IRB training. This training covers the procedures and practices each SEED site intends to use to protect the confidentiality of the data collected or distributed as part of the SEED study. Study personnel (site staff, contractors, staff, guest researchers, fellows, research assistants and anyone who has approved access to study data) are required at all times to maintain and protect the study 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 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, 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 regard to the SEED study. 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
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 the Scientific and Research Project Records Control Schedule. At the end of SEED Teen, the PII will be retained, as per the consent agreement, to enable future contact with the participants. At the conclusion of the overall SEED program, all PII will be retained by CDC for one year as per the CDC Scientific and Research Project Records Control Schedule. After one year, all identifiable information must be destroyed in accordance with the Certificate of Confidentiality approved application. The study periods for SEED and SEED Teen are defined to include data analysis and publication. The end of the study period will be considered to be 1 year after the final manuscript from a SEED data analysis is submitted for publication. No identifiable information will be retained or transferred to the National Archives. Identifying information will be collected during the data collection period and will be kept private in a separate file from the other data collection elements. Only the research staff will have access to a list linking a participant's study ID to his/her study data. Each SEED Teen site's data will be stored separately from all others and no site will have the means to access the personally identifiable data stored by another site unless granted permission to do so for specific study purposes.

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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: Access to PII follows a least privilege model. Access to PII follows a least privilege model. SEED staff receive study specific confidentiality training in addition to IRB training. This training covers the procedures and practices each SEED site intends to use to protect the confidentiality of the data collected or distributed as part of the SEED study. Study personnel (site staff, contractors, staff, guest researchers, fellows, research assistants and anyone who has approved access to study data) are required at all times to maintain and protect the study 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 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, 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 regard to the SEED study. Technical Controls: Access to PII follows a least privilege model. The PII will be secured in the CADDRE system. The CADDRE System Security Plan describes the user privileges and the IRB documents outline who should have access to what PII maintained in the system. Secure logins will be used to prevent unauthorized access from the application. CADDRE enforces a limited number of invalid access attempts by a user before lockout. 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 each SEED site to protect information, buildings, and equipment from unauthorized intrusions, environmental hazards, and natural hazards.

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

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	Reviewer Questions	Answer
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
Reviewer Notes		

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	Reviewer Questions	Answer
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	Beverly E. Walker -S Digitally signed by Beverly E. Walker -S Date: 2018.02.16 10:26:28 -05'00'	HHS Senior Agency Official for Privacy