

Privacy Impact Assessment Form

v 1.47.4

Status

Form Number

Form Date

Question

Answer

1 OPDIV:

2 PIA Unique Identifier:

2a Name:

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.

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

11 Describe the purpose of the system.	Research Electronic Data Capture (REDCap) is a data management platform for collection, analysis, and visualization
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.)	REDCap is a data collection tool offered to CDC programs in support of public health research and public health emergency response. REDCap projects and data requirements vary from public health research, laboratory research, emergency
13 Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	REDCap is an open source software develop for scientific research. The application was developed and maintained by Vanderbilt University. Updates are managed and distributed
14 Does the system collect, maintain, use or share PII?	<input checked="" type="radio"/> Yes <input type="radio"/> No
15 Indicate the type of PII that the system will collect or maintain.	<input type="checkbox"/> Social Security Number <input checked="" type="checkbox"/> Date of Birth <input checked="" type="checkbox"/> Name <input checked="" type="checkbox"/> Photographic Identifiers <input type="checkbox"/> Driver's License Number <input type="checkbox"/> Biometric Identifiers <input checked="" 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 checked="" type="checkbox"/> Medical Records Number <input checked="" type="checkbox"/> Medical Notes <input type="checkbox"/> Financial Account Info <input checked="" type="checkbox"/> Certificates <input checked="" type="checkbox"/> Legal Documents <input checked="" type="checkbox"/> Education Records <input checked="" type="checkbox"/> Device Identifiers <input checked="" type="checkbox"/> Military Status <input checked="" type="checkbox"/> Employment Status <input checked="" type="checkbox"/> Foreign Activities <input type="checkbox"/> Passport Number <input type="checkbox"/> Taxpayer ID
16 Indicate the categories of individuals about whom PII is collected, maintained or shared.	<input checked="" type="checkbox"/> Employees <input checked="" type="checkbox"/> Public Citizens <input checked="" type="checkbox"/> Business Partners/Contacts (Federal, state, local agencies) <input checked="" type="checkbox"/> Vendors/Suppliers/Contractors <input checked="" type="checkbox"/> Patients Other <input type="text"/>
17 How many individuals' PII is in the system?	500-4,999
18 For what primary purpose is the PII used?	Most REDCap data projects do not contain PII. When PII is solicited, it is because the CDC 's Principal Investigator (PI) for each project leading that research project judges that PII may be important for that public health response, e.g. clinical trial follow-up after vaccine administration. The PI is responsible for Office of Management and Budget (OMB) clearance and communication about PII to respondents.

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.	N/A	
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.	Public Health Service Act, Section 306(b) (42 U.S.C. 242k)	
22 Are records on the system retrieved by one or more PII data elements?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
23 Identify the sources of PII in the system.	<p>Directly from an individual about whom the information pertains</p> <ul style="list-style-type: none"> <input type="checkbox"/> In-Person <input type="checkbox"/> Hard Copy: Mail/Fax <input type="checkbox"/> Email <input type="checkbox"/> Online <input type="checkbox"/> Other <p>Government Sources</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Within the OPDIV <input type="checkbox"/> Other HHS OPDIV <input checked="" type="checkbox"/> State/Local/Tribal <input type="checkbox"/> Foreign <input type="checkbox"/> Other Federal Entities <input type="checkbox"/> Other <p>Non-Government Sources</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Members of the Public <input type="checkbox"/> Commercial Data Broker <input type="checkbox"/> Public Media/Internet <input checked="" type="checkbox"/> Private Sector <input checked="" type="checkbox"/> Other 	
23a Identify the OMB information collection approval number and expiration date.	<p>If required, each individual project's program/Principle Investigator (PI) is responsible for obtaining the OMB information collection approval number. The PI is notified of and acknowledges this responsibility through the completion and acceptance of the REDCap Project Request Form. If OMB clearance is require for a project, the REDCap Project Request Form requires disclosure of the corresponding OMB information collection approval number and expiration date.</p>	
24 Is the PII shared with other organizations?	<input type="radio"/> Yes <input checked="" type="radio"/> No	

<p>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.</p>	<p>For all REDCap data projects, CDC requires the governmental or non-governmental organizations (as defined in Q23 above) contributing the information to capture consent with the research or public health event by capturing a certified electronic signature for each participant in the research protocol or study. Each individual project's program/Principle Investigator (PI) is responsible for ensuring processes are in place to notify individuals that their personal information will be collected. The PI is notified of and acknowledges this responsibility through the completion and acceptance of the REDCap Project Request Form.</p>	
<p>26 Is the submission of PII by individuals voluntary or mandatory?</p>	<p><input checked="" type="radio"/> Voluntary <input type="radio"/> Mandatory</p>	
<p>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.</p>	<p>For all REDCap data projects, CDC requires the governmental or non-governmental organizations (as defined in Q23 above) contributing the information to capture consent with the research or public health event by capturing a certified electronic signature for each participant in the research protocol or study. Each individual project's program/principle investigator (PI) is responsible for implementing methods for individuals to opt-out of the collection or use of their PII. The PI is notified of and acknowledges these responsibilities through the completion and acceptance of the REDCap Project Request Form.</p>	
<p>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.</p>	<p>For all REDCap data projects, CDC requires the governmental or non-governmental organizations (as defined in Q23 above) contributing the information to capture consent with the research or public health event by capturing a certified electronic signature for each participant in the research protocol or study. Each individual project's program/Principle Investigator (PI) is responsible for implementing processes 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). The PI is notified of and acknowledges this responsibility through the completion and acceptance of the REDCap Project Request Form.</p>	
<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>Patient PII data are collected by governmental or non-governmental organizations (as defined in Q23 above) and are submitted to CDC in support of Public Health research or events. CDC has no direct involvement in the PII collection process or contact with the individuals. Each individual project's program/Principle Investigator (PI) is responsible for periodic reviews of the integrity, availability accuracy, and relevancy of PII collected. The PI is notified of and acknowledges this responsibility through the completion and acceptance of the REDCap Project Request Form.</p> <p>CDC relies upon those organizations to have appropriate processes and procedures in place to resolve individual concerns regarding the accuracy and handling of the PII prior to submission. However, upon request, the REDCap support team will help research system logs or otherwise assist the PIs with their investigations.</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>Each individual project's program/Principle Investigator (PI) is responsible for periodic reviews of the integrity, availability accuracy, and relevancy of PII collected. The PI is notified of and acknowledges this responsibilities through the completion and acceptance of the REDCap Project Request Form.</p>										
<p>31 Identify who will have access to the PII in the system and the reason why they require access.</p>	<table border="1"> <tr> <td data-bbox="727 310 951 443"> <input checked="" type="checkbox"/> Users </td> <td data-bbox="951 310 1411 443"> Users require access for data entry (open to all authorized users); Survey Design and Data analysis (restricted to CDC badged staff and direct </td> </tr> <tr> <td data-bbox="727 443 951 575"> <input checked="" type="checkbox"/> Administrators </td> <td data-bbox="951 443 1411 575"> Administrators require access for Application, User, Database, and Server Management (restricted to CDC badged staff and direct contractors). </td> </tr> <tr> <td data-bbox="727 575 951 646"> <input type="checkbox"/> Developers </td> <td data-bbox="951 575 1411 646"> </td> </tr> <tr> <td data-bbox="727 646 951 779"> <input checked="" type="checkbox"/> Contractors </td> <td data-bbox="951 646 1411 779"> Direct contractors require access for data entry, Survey Design and Data analysis. Direct Contractors may act as Administrators also. </td> </tr> <tr> <td data-bbox="727 779 951 850"> <input type="checkbox"/> Others </td> <td data-bbox="951 779 1411 850"> </td> </tr> </table>	<input checked="" type="checkbox"/> Users	Users require access for data entry (open to all authorized users); Survey Design and Data analysis (restricted to CDC badged staff and direct	<input checked="" type="checkbox"/> Administrators	Administrators require access for Application, User, Database, and Server Management (restricted to CDC badged staff and direct contractors).	<input type="checkbox"/> Developers		<input checked="" type="checkbox"/> Contractors	Direct contractors require access for data entry, Survey Design and Data analysis. Direct Contractors may act as Administrators also.	<input type="checkbox"/> Others	
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<input type="checkbox"/> Others											
<p>32 Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.</p>	<p>The Business Steward is limiting access to the smallest possible number of people necessary to access PII data for conducting official responsibilities through specific Role-based</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>Least privilege, Role Based Access methods are used to allow those with access to PII to only access the minimum amount of information necessary to perform their job. The system administrator is responsible for setting up the user access to the system based on the CDC user ID and the permissions assigned to it.</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>All CDC personnel are required to complete annual Security and Privacy Awareness Training.</p>										
<p>35 Describe training system users receive (above and beyond general security and privacy awareness training).</p>	<p>Third party governmental and non-governmental data contributors receive role-based training regarding system access rules of behavior on a study by study basis.</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>										

37 Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific records retention schedules.

Each program using REDCap is responsible for applying its own existing records retention schedules to PII data, and schedules will vary across programs.

Specifically to REDCap, the records are maintained in accordance with General Records Schedule (GRS) and comply with CDC Records Control Schedule (RCS). Final reports are created to document programmatic decisions, policies, and other related issues and are maintained permanently (CDC RCS, B-321, 2&4). Input data of Non-electronic records manually data entered are maintained and disposed of when no longer needed: GRS 20.2a.4. Other input/output records are disposed of when no longer needed: GRS 20.2a.4, 20.2d, and 20.6. Disposal methods include erasing computer tapes, burning or shredding paper materials or transferring records to the Federal Records Center when no longer needed for evaluation and analysis.

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

Administrative controls: Completion of training requirements; risk analyses performed annually; branch management reviewing access requests and granting minimal amount of access.

Technical controls: Users are authenticated and data secured using operating system and server security, administered by the local system administrator. PII data is encrypted at rest and in transits with access restricted to specific authorized users as required by HHS and CDC policy. All user access to the REDCap web application is authenticated via CDC's Digital Support Office-Secure Access Management System (SAMS), including authorized CDC users.

Physical- The server is housed on CDC property with gate guards at the entrances to the property, individual user access credentials are required for each non-public building , floor, and office. Closed Circuit TV is also used by the internal security guards to check for and grant access to authorized individuals.

General Comments

OPDIV Senior Official for Privacy Signature