US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

08/26/2025

OPDIV:

NIH

Name:

NIEHS DLH Infinibyte-Qualtrics (DLH-IQ)

PIA Unique Identifier:

P-3997396-381514

The subject of this PIA is which of the following?

Minor Application (child)

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

No

Does the system include a Website or online application available to and for the use of the general public?

Yes

Identify the operator.

Agency

Is this a new or existing system?

New

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

Describe the purpose of the system.

The National Institute of Environmental Health Sciences (NIEHS) DLH-Infinibyte Qualtrics (IQ) provides a centralized infrastructure to provide Principal Investigators (PIs) within the Epidemiology Branch, Division of Intramural Research, with epidemiological, scientific, technical, data management, managerial, clerical, and statistical support. DLH (not an acronym) assists the Government by identifying and enrolling research participants and administering, managing, and conducting epidemiological studies designed and conducted by the Epidemiology Branch PIs alone, or in collaboration with other scientists inside or outside of NIEHS, and by carrying out directed analyses of the data and biological and environmental samples from such studies, for ultimate publication by Epidemiology Branch Investigators in scientific journals.

Describe the type of information the system will collect, maintain (store), or share.

The types of information collected, maintained, and stored include:Study participant information: name, address, date of birth, phone numbers, email addresses, medical records, birth and death certificate information, genetic information, Global Positioning System (GPS) coordinates,

employment status, mother’s maiden name, and social security number (SSN).

Survey/questionnaire data about risk factors for disease and health/disease status including demographic information (sex, race, ethnicity, income, occupation, education), environmental exposures, lifestyle factors and behaviors (diet, exercise, substance use, sleep), family and residential history, medical conditions and diagnoses, medications, etc.

Measurement data including anthropometric (the science that defines physical measures of a person's size, form, and functional capacities), physiological, and other tests such as lung function, ultrasounds, etc.

Biological and environmental specimen data (blood, urine, dust, nail clippings, saliva, stool) and assay results.

Username and password are collected and stored for the Common Authentication Framework (CAF) Manager; for all other applications included in this system, users log in using the NIH Identity, Credential, and Access Management (IAM) Services which maintains its own unique privacy impact assessment (PIA) on record, with all legal authorities documented. The purpose of IAM Services is to authenticate and authorize all users and computers in a Windows domain type network assigning and enforcing information security policies for all computers and installing or updating software. The IAM Services collects unique user credentials and stores them in an encrypted format. The IAM Service is an essential service which facilitates and governs network access to various resources.

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

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Does the system collect, maintain, use or share PII?

Yes

Indicate the type of PII that the system will collect or maintain.

Social Security Number
Date of Birth
Name
Mother's Maiden Name
E-Mail Address
Mailing Address
Phone Numbers
Medical Records Number
Medical Notes
Certificates
Employment Status
Genetic and demographic Information, GPS Coordinates, lifestyle factors, specimen and anthropometric data
Username and password, birth and death certificate information

Indicate the categories of individuals about whom PII is collected, maintained or shared.

Employees
Public Citizens
Patients

How many individuals' PII is in the system?

100,000-999,999

For what primary purpose is the PII used?

Environmental health research including tracing of research participants to maintain current contact information for longitudinal studies requiring participant retention over time.

Describe the secondary uses for which the PII will be used.

N/A

Identify legal authorities governing information use and disclosure specific to the system and program.

Section 913 and 306 of the Public Health Service (PHS) Act (42 U.S.C. § 299b-2 and 242k(b)). Sections 924(c) and 308(d) of the PHS Act (42 U.S.C. 299c-3(c) and 242m(d)), and 44 U.S.C. 3101.

Are records on the system retrieved by one or more PII data elements?

Yes

Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being use to cover the system or identify if a SORN is being developed.

09-25-0200 Clinical, Basic and Population-based Research Studies of the National Institutes of

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

In-Person

Email

Online

Paper

Government Sources

Within the OPDIV

Other HHS OPDIV

State/Local/Tribal

Non-Governmental Sources

Public

Private Sector

Identify the OMB information collection approval number and expiration date

N/A. Public Law 114-255, Section 2035, exempts research conducted by NIH from Paperwork Reduction Act (PRA) requirements.

Is the PII shared with other organizations?

No

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.

All informed consent documents inform research participants about types of personally identifiable information (PII) to be collected, how data will be used, who to contact to obtain additional information, and the security procedures used to ensure confidentiality. Research subjects are also informed that they can withdraw from the study at any time without consequence.

Is the submission of PII by individuals voluntary or mandatory?

Voluntary

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.

All research participants can opt out of study participation at any time via email, mail, or phone.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.

For changes of data use outside of what was previously agreed to, participants are contacted and re-consented.

In cases of any compromise or data breach, participants are contacted to inform them of the incident.

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.

During the informed consent process, research subjects are provided with contact information for the coordinating center, the investigator, and the Institutional Review Board (IRB) and are encouraged to inform any of these parties of any misuse of PII. Individuals can use any of these contacts if they feel that any information, including their own PII, is inaccurate or has been inappropriately obtained, misused, or inappropriately disclosed.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.

Study team members will generate and provide periodic review reports of updates to the study data.

Study team members review PII data sources to ensure that they remain relevant and necessary for fulfilling the system's purpose.

Identify who will have access to the PII in the system and the reason why they require access.

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

DLH-IQ has established procedures defining Account and Access Management, defining how accounts are created, modified, and disabled as well as data access processes and separation of duties. Only pre-defined Project Managers can make account and access requests. Only designated Information Technology Staff can create accounts and enable access. When access requests are made, Information Technology Staff verify the requestor against a control roster to ensure they are permitted to make the request. All access requests are documented in the DLH-IQ Service Desk System.

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.

Least privilege access is being followed to grant permissions. An NIH IAM account is used to ensure Administrators, Developers,and Users have separate permissions based on roles.

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.

According to NIH policy,all personnel who manage or operate NIH applications must successfully complete annual security and privacy awareness training. Training is completed on the http: //irtsectraining.nih.gov site with valid NIH credentials.

Describe training system users receive (above and beyond general security and privacy awareness training).

Privileged users are required to take mandatory role-based training.

Additional training may be required, depending on the study and specific study function, and are described in the specific study protocols."

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

Yes

Describe the process and guidelines in place with regard to the retention and destruction of PII.

01-003, Records of All Other Intramural Research Projects. Cut off annually at termination of project/program or when no longer needed for
scientific reference, whichever is longer. Destroy 7 years after cutoff (DAA-0443-2012-0007-0003).

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

Physical: The SUPS (Support Services) System will be hosted at the DLH-IQ Secure Data Center

(SDC) located in northern Virginia . The SDC operates at a tier-4, secure colocation facility where physical access to the hardware is limited only to a select number of administrators and is secured through a number of physical access controls including biometric hand scanners, 24/7 guards, pin access codes, private cage access codes and man traps. The facility contains redundancy for power and standby generators, cooling and environmental systems, and a pre-stage fire-suppression system.

Technical: Data is transferred to the SDC using a Secure File Transfer (SFTP) service. The data that resides at the SDC, while at rest, is stored on encrypted drives that are dedicated to the project. DLH-IQ manages access to virtual machines and data enclaves through NIH IAM Services utilizing the “least privilege” concept.

Administrative: Access to PII is permitted only through authorization by the Project Director, after all required data use agreements are signed and confidentiality training performed.
All employees, direct contractors and off-site contractors must have valid credentials with specific access granted.

Identify the publicly-available URL:

https://epishare.niehs.nih.gov/
https://sftp.infinibytecloud.com
Note: web address is a hyperlink.

Does the website have a posted privacy notice?

Yes

Is the privacy policy available in a machine-readable format?

Yes

Does the website use web measurement and customization technology?

Yes

Select the type of website measurement and customization technologies is in use and if it is used to collect PII.

Does the website have any information or pages directed at children uner the age of thirteen?

No

Does the website contain links to non- federal government websites external to HHS?

Yes

Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?

Yes