US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

03/27/2026

OPDIV:

NIH

Name:

Personalized Environment and Genes Study

PIA Unique Identifier:

P-4708769-688107

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 purpose of Personalized Environment and Genes Study (PEGS) is to serve as a biological and environmental specimen resource for investigators to screen for genetic polymorphisms, conduct whole genome sequencing and whole exome sequencing to identify genetic changes that can cause disease, and to explore differences in hormones, dietary factors, and/or chemical or toxins in the blood or urine that may affect health.

PEGS, as a controlled access data repository (CADR), provides long-term storage for, or provides access to, data for research purposes.

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

The following personally identifiable information (PII) is collected in PEGS :

Name (personal, collaborators, principal investigator (PI))

Email

Institution

phone numbers (participants, next of kin, and emergency contacts)

mailing address (participants, next of kin, and emergency contacts)

date of birth (DoB), race, ethnicity, sex

Education records (level of education) and employment status (including occupation history and income)

medical notes and medical information (including subject identification number, medical history, study visit dates, medical assessments, HIV-status, biometrics, ultrasounds images, X-ray images, body scans, single nucleotide polymorphisms (SNPs) genotypes, whole genome sequencing, whole exome sequencing, wearable device data and identifiers, human biospecimens (blood, urine, tissue, nails, hair, saliva, sputum, stool, household dust, and teeth), dates of admission/discharge/diagnosis/procedure)

medical record numbers

Internal NIH users administering the system log in using the NIH Identity, Credential, and Access Management (IAM) Services which maintains its own unique PIA on record, including 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 collect unique user credentials and stores them in an encrypted format. The IAM Services are 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.

The purpose of Personalized Environment and Genes Study (PEGS) is to serve as a biological and environmental specimen resource for investigators to screen for genetic polymorphisms, conduct whole genome sequencing and whole exome sequencing to identify genetic changes that can cause disease, and to explore differences in hormones, dietary factors, and/or chemical or toxins in the blood or urine that may affect health.

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

Yes

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

Date of Birth
Name
E-Mail Address
Mailing Address
Phone Numbers
Medical Records Number
Medical Notes
Education Records
institution
race, ethnicity, sex

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?

10,000-49,999

For what primary purpose is the PII used?

PII is used to maintain the integrity of the data and to allow for participants to identify themselves for recontact efforts and cohort maintenance, and to link to electronic health records data.

It is also used when analyzing the data for research purposes. subject identification numbers are generated and mapped to the existing participants so that the analyst data set cannot be matched back to the study data set by anyone receiving the analysis data set.

To contact participants to volunteer to participate in Institutional Review Board (IRB) approved PEGS follow-up studies investigating gene-environment interactions in risk of disease.

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.

42 USC § 285l
42 U.S. Code § 241
42 U.S. Code § 282
42 U.S. Code § 284

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
Hardcopy
Email
Government Sources
Within OPDIV
Other HHS OPDIV
State/Local/Tribal
Non-Governmental Sources
Public

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?

Yes

Identify with whom the PII is shared or disclosed and for what purpose.

Describe any agreements in place that authorizes the information sharing or disclosure.

Depending on the data types and organization that PEGS is sharing information with, PEGS uses Materials Transfer Agreements, Data Use Agreements, and Memorandums of Understanding to authorize the sharing of data.

Describe the procedures for accounting for disclosures.

All disclosures are documented through the NIEHS Study Review form and are only made to investigators with IRB approved protocols that have been documented.

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 provide their information at the time of consenting to participate in PEGS. The consent form explains how their information will be used. No other notifications are given unless participants are selected for inclusion in a voluntary PEGS follow-up study.

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.

Individuals may decide not to consent to participate in the PEGS. An individual who is a participant can decide at any time to withdraw from the registry and we will no longer use their PII for the purposes of the registry.

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

Participants are notified during the annual recontact process or at other times during the year for special group of any changes that have been made to data uses and obtain their consent to use their data for those uses. We do not institute changes until we have received a reply from the participant consenting to the changes. If we do not obtain their consent, we flag that in the system and only use the data for purposes for which the participant has consented.

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.

Individuals can contact the telephone or email helpline which is staffed by research assistants. Assisstants refer the participant to the NIEHS PI. NIEHS staff and PI work together to determine if a problem had occurred and report back to the participant on the results of the investigation and actions taken to resolve the situation and to prevent any reoccurrence, if needed.

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

Participants are recontacted on a yearly basis to verify and update their contact information. At this time any inaccurate information can be corrected in the system. We also periodically run exception reports to look for outliers in the data, do an analysis and make corrections to the data as needed.

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.

User access is provided only to PEGS staff who need it to do the day-to-day activities of managing the registry.

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.

PEGS staff members are assigned a role-based user ID which allows them access only the information they need to perform their job tasks.

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 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).

System users receive training in an overview of the PEGS and what it is, how to consent participants, how to respond to participant questions or concerns, how to access the database, enter and edit data, and generate reports (DAA-0443-2012-0007-0010).

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.

03-005, Patient Medical Records. Cut off patient case file annually after 5 years of inactivity. Destroy when case file
is no longer needed for scientific reference.

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 Controls: The Information Technology (IT) hardware used to host PII is located in a secure data center facility. The facility is only open to authorized personnel whose access is monitored by locking doors with badge readers for both ingress and egress. Each discrete ingress and egress event is logged. The facility is under 24-hour surveillance by facilities security for security and environmental hazards.

Technical Controls: The IT hardware and software used to host the PII is segregated from default commodity networks to prevent unauthorized or malicious access. Access controls lists and event logs are kept and monitored to detect unauthorized, suspicious or malicious activity. Access lists are restricted to approved IT technical personnel. Two factor authentication must be used for access.

File integrity and auditing software are employed on hardware.

Administrative Controls: All technical personnel who access IT systems which contain PII have met background investigation criteria for public trust positions. All personnel have taken mandatory security training and awareness classes and refreshers. Personnel accessing these systems use a privileged and separate account for administrative access to systems.

Identify the publicly-available URL:

https://joinastudy.niehs.nih.gov
https://www.niehs.nih.gov/research/atniehs/labs/crb/studies/pegs/index.cfm

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